

TITLE: Application Requirements for New Projects Funded or Sponsored by the Office of Research and Development (ORD) Services

1.0 PURPOSE

This Standard Operating Procedure describes the application requirements that must be met by Principal Investigators (PIs) or Study Chairs (SCs) and Local Site Investigators (LSIs) for submitting new projects involving multi-site human participant research to the VA Central IRB for review. It also describes the policies and procedures the VA Central IRB administrative staff members follow when conducting administrative reviews of new project applications and scheduling projects for review by the VA Central IRB.

2.0 REVISION HISTORY

Date of Initial Approval	April 16, 2009
Revision Dates	April 16, 2009 September 23, 2009 March 17, 2010

3.0 SCOPE

3.1 This SOP applies to new ORD multi-site projects designated by one of the ORD services for review by the VA Central IRB. The ORD services designating the projects for review by the VA Central IRB are:

- Clinical Science Research and Development (CSR&D), to include the Cooperative Studies Program (CSP); currently all new CSP studies are submitted to the VA Central IRB.
- Health Services Research and Development (HSR&D), to include the Quality Enhancement Research Initiative (QUERI)
- Rehabilitation Research and Development Service (RR&D)

3.2 This SOP does not pertain to requests for exemption, which are covered in VA Central IRB SOP 107, Requests for Exemption Review and Determination.

4.0 POLICY

4.1 The VA Central IRB only accepts new multi-site projects for review that have been referred to it by one of the ORD funding services listed in paragraph 3.1. These projects have gone through a scientific merit review as part of the funding process. A single site pilot project that has the potential to expand to a multi-site project will also be accepted for review.

4.2 It is the policy of the VA Central IRB that a project is not scheduled for initial review by the VA Central IRB until all application requirements as detailed in this SOP are met. New project applications and associated documents must contain a sufficient description of the proposed research for the VA Central IRB to make an informed determination regarding all required regulatory approval criteria, as well as VA and VA Central IRB requirements.

5.0 DEFINITIONS

See VA Central IRB SOP 128, Definitions Used in VA Central IRB SOPs.

6.0 RESPONSIBILITIES

6.1 Principal Investigator /Study Chair (PI/SC) – The PI/SC is responsible for the overall conduct of the project and for ensuring implementation of the project is in compliance with VA and all other requirements for the conduct of human research. The PI/SC serves as the main point of contact for the VA Central IRB regarding the project. For the purposes of this SOP, the PI/SC is responsible for the following:

6.1.1 The PI/SC, or designee, submits all required documentation regarding the project to the VA Central IRB. This documentation includes but is not limited to the VA Central IRB Form 108, Principal Investigator/Study Chair New Project Application and all associated attachments (Attachment 1).

6.1.2 For some projects, there may be one or more Co-PI/SCs designated. For these projects, one of the Co-PI/SCs must complete the VA Form 108 and the other Co-PI/SC(s) must complete a VA Form 108a (Attachment 2), Co-PI New Project Supplement, and submit this form with the VA Central IRB Form 108 as part of the complete application package.

6.1.3 A PI/SC may also serve as the LSI for his or her home site. In this case, the PI/SC also prepares the VA Central IRB Form 104, Local Site Investigator Application (Attachment 3), to include all associated attachments, for the specific site.

6.1.4 The PI/SC recruits the LSIs for each of the other participating sites as applicable. The PI/SC is responsible for reviewing all the LSI applications to ensure consistency with the PI/SC application and/or any modifications that are requested by the VA Central IRB. The PI/SC then submits the LSI applications to the VA Central IRB. The PI/SC is responsible for ensuring that no research begins at any of the engaged sites in the study until all required approvals have been received.

6.2 Local Site Investigator (LSI) – The LSI must provide a rationale for any differences between the PI/SC and LSI application. The LSI is responsible for all aspects of the research project conducted at the local site and for ensuring

compliance at that site with all VA and other requirements for the conduct of human research. For the purposes of this SOP, the LSI recruits the local site project team and prepares the LSI Application for the specific participating local site. The LSI is responsible for not beginning any research project at that site until all required approvals have been received.

6.3 Project Team Members – All project team members at each participating local site, including the PI/SC and LSIs, are responsible for following the project plan, identifying any conflicts of interest, and adhering to all VA and other requirements regarding the conduct of human research. They are also responsible for remaining current on all VA required training on the protection of human research participants, as well as VA data security and privacy requirements.

6.4 Associate Chief of Staff for Research and Development (ACOS/R&D) – For the purposes of this SOP, the ACOS/R&D is responsible for reviewing the PI/SC New Project Application or the LSI New Project Application as applicable, prior to submission to the VA Central IRB. The ACOS/R&D signs the applicable application certifying the following on behalf of the PI/SC site and/or the local participating site:

- The PI/SC, or LSI as applicable, and the rest of the project team have the experience and training needed to conduct the project.
- All the site project team members have been appropriately credentialed and privileged and they have all completed required VA training in the protection of human research participants and if applicable, Good Clinical Practices.
- The local facility has reviewed or is in the process of reviewing any potential conflicts of interest of local site project team members and the results of the review have been or will be forwarded to the VA Central IRB.
- The facility and the PI/SC and/or LSI as applicable have the resources to support the functions and operations of the project as detailed
- If there are any local context issues requiring review by the VA Central IRB that these have been identified in the application
- The project will not begin at the local participating facility until the PI/SC, or LSI as applicable, has received written approval to initiate the study in accordance with VHA Handbook 1200.01.

6.5 VA Central IRB – The VA Central IRB is responsible for fulfilling all responsibilities and performing all functions of an IRB of record as specified in VHA Handbook 1200.05 for all projects it receives for review. Once a project is approved, the VA Central IRB is responsible for overseeing the project and conducting continuing review as required.

6.6 VA Central IRB Coordinator – For the purposes of this SOP, the assigned VA Central IRB Coordinator is responsible for completing the following for all projects assigned:

- Entering the new project application into the VA Central IRB Protocol Tracking System
- Performing administrative review of submitted project applications to ensure they are complete
- Working with the PI/SC, LSIs, and local site points of contact to obtain any missing or incomplete documentation/information
- Completing VA Central IRB Form 109a, Site Tracking Log (Attachment 3), and using it to track all local site application submissions for a specific project
- Completing the VA Central IRB Form 109b, Administrative Checklist for PI/SC New Project Application (Attachment 4)
- Completing the VA Central IRB Form 109c, Administrative Checklist for Local Site Investigator Applications (Attachment 5)

6.7 VA Central IRB Administrator – For the purposes of this SOP, the VA Central IRB Administrator is responsible for the following:

- Coordinating application deadlines and VA Central IRB meeting dates with the VA Central IRB Co-Chairs, ensuring these are communicated to the project teams, and publishing them on the VA Central IRB website
- Working with the PI/SC and local site project teams to educate them on new project application requirements and procedures
- Ensuring that the participating local sites for a new project have entered into an MOU with the VHACO and listed the VA Central IRB as an IRB of record on their FWA
- Educating participating local sites on their responsibilities under the MOU through the use of webinars, informative website content, conference calls, and in-person seminars
- Assigning new projects upon receipt to a VA Central IRB Coordinator
- Reviewing the VA Central IRB Forms 109 after they have been completed by the VA Central IRB Coordinators
- Assisting the VA Central IRB Coordinators in obtaining missing documentation and in communicating with the PI/SC, LSIs, and the local sites as needed
- Coordinating the workload to ensure that it is evenly distributed among the VA Central IRB Coordinators
- Ensuring all new projects submitted are entered into the Master Study Status log and that this log is kept up-to-date
- Ensuring that projects are scheduled for review by the IRB in a timely manner while still allowing IRB members sufficient time to perform a thorough review

7.0 PROCEDURES

7.1 Designating Projects to be Submitted to the VA Central IRB and Pre-Submission Requirements.

7.1.1 Currently, the Cooperative Studies Program Central Office has determined all new CSP studies will be submitted to the VA Central IRB for review. The other ORD services (HSR&D, QUERI, and RR&D) make this decision in consultation with VA Central IRB administrative officials and the PIs of the applicable projects. Once the ORD service decides that the VA Central IRB will review a project, an investigator, whether the investigator is the PI/SC or an LSI, cannot choose to use another IRB.

7.1.2 Each ORD service, or in some instances the PI/SC, provides the following information to the VA Central IRB Administrator upon a project being designated for review by the VA Central IRB:

- Title of the project and assigned ORD service project number if applicable
- Name and contact information for the PI/SC
- The name and point of contact for the project manager or national coordinator
- A list of potential participating sites
- A copy of the scientific merit review results if applicable

7.1.3 The VA Central IRB Administrator reviews the list of potential participating sites to ensure that all identified sites have an active MOU on file and have listed the VA Central IRB on their local facility FWA.

7.1.3.1 The VA Central IRB Administrator contacts sites that have not listed the VA Central IRB as an IRB of record and assists them in submitting all required documentation in accordance with VA Central IRB SOP 101, VA Central IRB Authority, Responsibilities, and Activities.

7.1.3.2 For projects under the Cooperative Studies Program (CSP), the VA Central IRB Administrator checks and ensures the following:

7.1.3.2.1 That the local facility in which the CSP Coordinating Center (CSPCC) involved in the project is housed has a current MOU on file and that the VA Central IRB is listed as an IRB of record as required by VA Central IRB SOP 101, VA Central Institutional Review Board (IRB) Authorities, Responsibilities, and Activities.

7.1.3.2.2 If the PI/SC is located at a facility that is not otherwise a participating site, that the PI/SC's site has a current MOU on file and that the VA Central IRB is listed as an IRB of record for the facility.

7.1.3.3 If the PI/SC is still in the process of recruiting local sites, the PI/SC may forward the names of the potential sites and LSIs to the VA Central IRB Administrator as they become known. The VA Central IRB Administrator ensures that regular contact is kept with the PI/SC during an ongoing site recruitment process to facilitate communication with the potential sites as soon as possible.

7.1.4 The VA Central IRB Administrator contacts the PI/SCs and project manager/national coordinator of designated projects and informs them of the following:

- PI/SC New Project Application requirements to include:
 - Application deadlines
 - Development of model forms for use by local participating sites in developing their own local forms for participants
 - Submission procedures
- IRB review procedures
- Whether potential participating sites have an active MOU with the VHACO and have updated their FWA listing the VA Central IRB as an IRB of record

7.1.5 The VA Central IRB Administrator invites the PI/SC, LSIs, and other members of the project team as applicable to one of the periodic investigator webinars presented by the VA Central IRB using the VA Live Meeting functionality. This educational webinar reviews the VA Central IRB application process and the various application forms, as well as providing a forum for investigator questions to VA Central IRB staff.

7.2 Application Requirements for PI/SCs.

7.2.1 The PI/SC should thoroughly review all application instructions and complete all required forms in order to ensure timely processing of the project by the VA Central IRB. The PI/SC is encouraged to contact the VA Central IRB Administrative Office throughout the process of completing the VA Central IRB Form 108, PI/SC New Project Application, and any other required forms, with questions or concerns. LSI Applications cannot be submitted until the main project application has been reviewed by the VA Central IRB.

7.2.2 Prior to submitting the application package to the VA Central IRB the PI/SC must ensure the following:

- The latest version of the grant application, or the protocol as applicable, and funding letter are attached to the application package
- That the documents checked on the front page of the VA Central IRB Form 108 are included as part of the package or are listed as "Pending" if they are not attached at the time of initial submission
- All informed consent forms are submitted in Microsoft Word format

- The signatures of the applicable Department Chief of the department the PI/SC is assigned, or the Chief of Staff if the PI/SC is a Department Chief, and the local ACOS/R&D are obtained certifying their review and concurrence with the contents of the package. If the ACOS/R&D is the PI/SC, the Chief of Staff signs in place of the ACOS/R&D.

7.2.3 The PI/SC must meet the above requirements and the following additional minimum application submission requirements in order for a project to be accepted for review by the VA Central IRB:

7.2.3.1 One signed copy of the application package must be submitted in electronic format via encrypted e-mail, encrypted CD/DVD, or uploaded onto the VA Central IRB SharePoint site. Other electronic methods of submission may be authorized on a case-by-case basis in consultation with the VA Central IRB Administrator based on local capabilities as long as all VA information security requirements are met. If a signed copy cannot be submitted electronically, the signature pages can be submitted via fax or express mail.

7.2.3.2 A PI/SC New Project Application package must be received by the VA Central IRB Administration Office no later than close of business on the published application deadline date in order to be considered for review at the next monthly convened meeting of the IRB.

7.2.3.3 If a PI/SC wants to request that the project be reviewed utilizing expedited review procedures, the PI/SC can complete a VA Central IRB Form 126, Request for Expedited Review (Attachment 4), and attach it to the application package.

7.3 Application Requirements for Local Site Investigators.

7.3.1 The PI/SC project team will provide the LSIs at the potential participating sites with a copy of the PI/SC New Project Application package as reviewed and approved by the VA Central IRB and assist the LSIs in compiling and preparing the LSI Applications. The PI/SC study team will set internal project deadlines for submission of the LSI Applications to the PI/SC study team. All LSI Applications are submitted to the VA Central IRB through the PI/SC project team unless an exception is requested and approved by both the PI/SC study team and the VA Central IRB Administrator.

7.3.1.1 The LSI is expected to thoroughly review all application instructions and complete all required forms to ensure timely processing of their Local Investigator Site Application by the VA Central IRB. The LSI may also contact the VA Central IRB Administrative Office with questions or concerns throughout the application process.

7.3.1.2 Model forms may have been provided to the LSI by the PI/SC, including a model informed consent document. Other than changes in

local site contact information, LSIs must ensure that any other changes made to the model forms are highlighted and justification for the changes provided. If changes to the model form are made, the LSI provides a copy of the form with the changes highlighted or shown in the track change function of Microsoft Word. A clean copy without highlights or tracked changes must also be included as part of the application package.

7.3.1.3 In addition to justification for any changes to the model forms provided by the PI/SC, the LSI must provide a rationale for any difference in the LSI Application and the information provided in the PI/SC Application and protocol.

7.3.1.4 Prior to submission of the VA Central IRB Form 104 and any attachments to the PI/SC project team, the LSI ensures a review has been completed by the applicable Department Chief or the LSI's supervisor and the local facility ACOS/R&D and both their signatures obtained.

7.3.2 The LSI submits a minimum of one signed electronic copy of the application package to the PI/SC study team. The PI/SC project team reviews the LSI Applications from the potential participating sites for consistency with the PI/SC Application and requests any changes as needed. The PI/SC then arranges for the submission of the LSI Applications to the VA Central IRB with the VA Central IRB Coordinator assigned to the project. The VA Central IRB Coordinator arranges for the PI/SC study team to upload the application to the VA Central IRB SharePoint site.

7.3.3 If an exception is granted by the PI/SC study team and the VA Central IRB Administrator, the LSI may submit the LSI Application directly to the VA Central IRB via the SharePoint site. Other methods of electronic submission may be authorized on a case-by-case basis in consultation with the VA Central IRB Administrator and the PI/SC project team based on local capabilities as long as all VA information security requirements are met.

7.3.4 If there are delays in the signing of the MOU, the update of the FWA for a local participating site, or in the submission of the LSI Application from a particular site, the VA Central IRB Coordinator consults with the PI/SC on a course of action. If desired, the PI/SC can add or drop a site from the project by informing the VA Central IRB in writing. If a site is added, the LSI Application for that site must be completed and submitted as described above.

7.4 Administrative Review by the VA Central IRB Administrative Office.

7.4.1 Upon receipt of the PI/SC application package, the VA Central IRB Administrator assigns a VA Central IRB Coordinator to the project based on workload. This Coordinator will continue as the VA Central IRB Coordinator of the project through the submission and approval of the LSI Applications unless the workload or the departure of a Coordinator requires a change.

7.4.1.1 The assigned VA Central IRB Coordinator logs the receipt of the PI/SC New Project Application into the Protocol Tracking System and the VA Central IRB Form 137, Master Study Status Log (Attachment 5). A VA Central IRB project tracking number is assigned based on the calendar year received and the next available number (e.g., 09-15). The VA Central IRB Coordinator emails the PI/SC confirming receipt of the project package and relaying the assigned tracking number.

7.4.1.2 The VA Central IRB Coordinator then prepares a VA Central IRB Form 109a, Site Tracking Log (Attachment 6). This form is used to track submission of the PI/SC Application and the Local Site Investigator Applications, as well as the MOU/FWA update status of the sites. In addition, this form is used to track the actions taken by both the VA Central IRB and the sites during the entire review and approval process for the project.

7.4.1.3 The VA Central IRB Coordinator then performs an administrative screening of the PI/SC Application Package using VA Central IRB Form 109b, Administrative Pre-Screening Checklist for PI/SC New Project Applications (Attachment 7).

7.4.1.3.1 If required documents are missing or there are other administrative issues that need to be addressed, the VA Central IRB Coordinator contacts the PI/SC study team. The VA Central IRB Coordinator advises the PI/SC study team of the date by which missing documents are needed or any outstanding issues need to be resolved if the project is to be reviewed at the next regularly scheduled convened meeting of the VA Central IRB.

7.4.1.3.2 The VA Central IRB Coordinator follows-up with the investigator in writing no less than once per month until the documents are received or the project is withdrawn by the PI/SC.

7.4.1.4 The VA Central IRB Coordinator documents all contacts with the PI/SC study team concerning study related issues and keeps hard copies, including e-mails, in a working administrative review folder. Routine contacts concerning such issues as logistics for submitting documents, availability for teleconferences etc., need not be included in this file, as long as they do not pertain to actual protocol-related issues. Upon completion of the administrative review process, all project documents, including any revisions, modifications, other pertinent documents, or correspondence discussing project issues and their resolution are filed in the official project folder. Procedures pertaining to the creation of the official folder can be found in VA Central IRB SOP 116, Maintenance of VA Central IRB Files.

7.4.1.5 Upon completion of the administrative screening process, the VA Central IRB Coordinator signs the VA Central IRB Form 109b

and forwards it and the complete project folder containing all pertinent documents and correspondence to the VA Central IRB Administrator.

7.4.1.6 The VA Central IRB Administrator reviews the project folder and approves the scheduling of the project for review by the VA Central IRB or, if the project is still not ready for review, the VA Central IRB Administrator contacts the PI/SC study team or any required clarifications or returns the project application package to the VA Central IRB Coordinator if there is missing documentation.

7.4.1.7 Upon approval by the VA Central IRB Administrator, the project folder is returned to the VA Central IRB Coordinator and prepared for review in accordance with VA Central IRB SOP 108, VA Central IRB Meeting Preparation and Administration, or VA Central IRB SOP 110, Expedited Review Process, as applicable.

7.4.2 Upon receipt of an LSI Application, the assigned VA Central IRB Coordinator updates the protocol tracking system and assigns the application a VA Central IRB number LSI Application number. This number will consist of the project number and a numeric value based on the order in which the LSI Applications are received, i.e., 07-15/1. A Local Site Investigator Application working administrative review file for the study is also created.

7.4.2.1 The assigned VA Central IRB Coordinator prepares and completes a VA Central IRB Form 109c, Administrative Pre-Screening Checklist for Local Site Investigator Applications (Attachment 8.)

7.4.2.1.1 If required documents are missing or there are other administrative issues, the VA Central IRB Coordinator contacts the LSI, or works through the PI/SC study team as requested, to obtain the documentation or a resolution of any other issues. The VA Central IRB Coordinator advises the LSI and/or the PI/SC study team of the date the documents are needed and of the outstanding issues that need to be resolved if the project is to be reviewed at the next regularly scheduled convened VA Central IRB meeting.

7.4.2.1.2 The VA Central IRB Coordinator follows-up in writing no less than once per month until the documents are received, the outstanding issues resolved, or the site is dropped as a participating site in the project by the PI/SC.

7.4.2.1.3 The VA Central IRB Coordinator documents all contacts with the LSIs and keeps hard copies of all written correspondence, including e-mails, in the official folder by site. The only exception is for routine contacts concerning logistical issues that have no bearing on the protocol or protocol-related issues. Upon completion of the administrative review process all project documents, including any revisions submitted and any

other pertinent documents discussing project issues and their resolution are filed in the official project folder per VA Central IRB SOP 116.

7.4.3 The assigned VA Central IRB Coordinator keeps the PI/SC study team, and LSI as applicable, updated on the status of the project and sends an update in writing as the project completes each step. The VA Central IRB Coordinator also updates the VA Central IRB Form 109a, Site Tracking Log as applicable.

7.4.4 All documents filed in the official project files, to include documents received from the project team, the completed pre-screening checklists, and any other correspondence pertinent to the content of the project, are also uploaded onto the VA Central IRB shared drive in accordance with VA Central IRB SOP 116.

7.4.5 All administrative screening files and project folders that are actively being worked on by VA Central IRB staff may be kept in the various offices of the VA Central IRB administrative staff who are working on them. All folders and files must be secured behind locked office doors when any of the administrative staff members leave their office during the course of the regular work day and secured in a locked cabinet within their office at the end of the work day. If the files are not being actively used on a daily basis by the VA Central IRB Coordinator, the files will then be stored in the Lektriever.

7.5 VA Central IRB Website. The VA Central IRB Administrator provides content to the PRIDE website developers as it relates to the VA Central IRB new project application process. This content contains the latest information about the VA Central IRB project application process and submission requirements including but not limited to the following:

- Information for Investigators and Local Participating Sites
- Application deadlines and meeting dates
- VA Central IRB SOPs and electronic forms for download
- Submission instructions and other information for investigators
- List of sites with approved and current MOUs already in place
- A "What's New" link to highlight new or revised items that have been added to the site
- Point of Contact Information

8.0 REFERENCES

8.1 38 CFR 16, Department of Veterans Affairs, Protection of Human Subjects

8.2 VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research

8.3 VHA Handbook 1058.03, Assurance of Protection for Human Subjects in Research

8.4 VHA Handbook 1108.04, Investigational Drugs and Supplies

8.5 45 CFR 46, Department of Health and Human Services, Protection of Human Subjects, Subparts B through D

8.6 21 CFR 50, U.S. Food and Drug Administration, Protection of Human Subjects

8.7 21 CFR 312, U.S. Food and Drug Administration, Investigational New Drug Application

8.8 21 CFR 361, U.S. Food and Drug Administration, Prescription Drugs for Human Use Generally Recognized as Safe and Effective and not Misbranded: Drugs Used for Research

8.9 21 CFR 600, U.S. Food and Drug Administration, Biological Products: General

8.10 21 CFR 812, U.S. Food and Drug Administration, Investigational Device Exemptions

8 Attachments

1. VA Central IRB Form 108, Principal Investigator/Study Chair New Project Application
2. VA Central IRB Form 104, Local Site Investigator Application
3. VA Central IRB Form 108a, Co-Principal Investigator/Study Chair New Project Application Supplement
4. VA Central IRB Form 126, Request for Expedited Review
5. VA Central IRB Form 137, Master Study Status Log
6. VA Central IRB Form 109a, Site Tracking Log
7. VA Central IRB Form 109b, Administrative Pre-Screening Checklist for PI/SC New Project Applications
8. VA Central IRB Form 109c, Administrative Pre-Screening Checklist for Local Site Investigator Applications

I have reviewed and approved the content of this SOP.


K. Lynn Cates, MD
Director, PRIDE

Date: 4/2/2010

Principal Investigator/Study Chair New Project Application



Principal Investigator/Study Chair Name:

Project Title:

Check to indicate application status:

☐ Initial ☐ Revised

Date:

Application Instructions

- The Principal Investigator (PI)/Study Chair (SC) must use this form to submit new research project applications to the VA Central IRB. The PI/SC's Supervisor and ACOS/R&D or Chief of Staff of the PI/SC's site also must complete a portion of this form.
- Submit this entire application in **two** forms: (1) a signed hard copy and (2) an electronic copy sent by encrypted e-mail. Each section must contain a response. Please ensure all responses are consistent with the approved funded project and the informed consent document if applicable. Other documents associated with this application as checked below should also be submitted electronically. Documents can be submitted in PDF or Microsoft Word format with the exception of the informed consent document. This document must be submitted in Microsoft Word. Please ensure the file name includes the document, last name of PI, and date (e.g., 108.PI.date).

Contents of Application Package (Please check all documents included in this package)

**Indicates a mandatory document for all studies*

- | | |
|--|--|
| <input type="checkbox"/> PI/SC New Project Application* | <input type="checkbox"/> HRC Minutes (For CSP studies only) |
| <input type="checkbox"/> Protocol* | <input type="checkbox"/> Scientific Merit Review Letter or Minutes* |
| <input type="checkbox"/> Conflict of Interest Determination(s)* | <input type="checkbox"/> Vulnerable Population Supplement (VA Central IRB 110 Series) |
| <input type="checkbox"/> Study Team Biosketches (Merit Review/NIH format)* | <input type="checkbox"/> Investigator's Drug Brochure |
| <input type="checkbox"/> Co-PI/SC New Project Application Supplement (VA Central IRB Form 108a) | <input type="checkbox"/> Investigator Device Information |
| <input type="checkbox"/> Model VA Research Informed Consent Form (VA Form 10-1086) | <input type="checkbox"/> Model Participant Instructions |
| <input type="checkbox"/> Prior Study Informed Consent Form (If this is a follow-up study) | <input type="checkbox"/> Model Recruitment Materials |
| <input type="checkbox"/> Request for Waiver or Alteration of Informed Consent (VA Central IRB Form 112a) | <input type="checkbox"/> Model Questionnaires or Surveys |
| <input type="checkbox"/> Model Consent for Use of Picture and/or Voice (VA Form 10-3202) | <input type="checkbox"/> Model VA Investigational Drug Information (VA Form 10-9012) |
| <input type="checkbox"/> Request for HIPAA Waiver of Individual Authorization (VA Central IRB Form 103) | <input type="checkbox"/> Data Collection Forms/Tools/Case Report Forms/etc. |
| <input type="checkbox"/> HIPAA Authorization | <input type="checkbox"/> Request for Expedited Review (VA Central IRB Form 126) |
| | <input type="checkbox"/> CSP Coordinating Center PI/SC New Project Application Supplement (VA Central IRB Form 108b) |

Please List any other documentation included in this package: (e.g., off-site waiver requests, tissue banking application/approval letter, Certificate of Confidentiality)

Please note: After the PI/SC New Project Application is approved, the PI/SC will be responsible for submitting all Local Site Investigator Applications (VA Central IRB Form 104) to the VA Central IRB. It is the PI/SC or Coordinating Center's responsibility to review all Local Site Investigator Applications to ensure consistency with the approved PI/SC New Project Application.

Submission Instructions

1. Please review your entire application prior to submission and ensure the following:

- All three required signatures have been obtained, to include the required signatures if submitting a Co-PI/SC New Project Application Supplement. If submitting a revised application, only the signature of the PI/SC is required. Ensure you include the version number/date for all revisions.
- The attachments match with what you have indicated on the preceding page. If any of the attachments have been revised, include the version number and date of revision.
- Unnecessary page breaks have been removed and any formatting errors have been corrected
- All sections of the application have been completed or marked "Not Applicable."

Please note for CSP studies only: All applications must either be submitted through the applicable CSP Coordinating Center or include a letter from the Coordinating Center attesting that the application is cleared for submission.

2. Please contact the VA Central IRB Administrator at 202-461-1813 or at va.central.irb@va.gov for instructions on how to upload the application and all associated documents to the VA Central IRB secure SharePoint site. You must have a valid VA e-mail address to gain access to the VA Central IRB SharePoint site.

For any other questions, please contact the VA Central IRB staff by e-mail at va.central.irb@va.gov or at the following toll-free number: 877-254-3130.

Project Title:

Section 1: Study General Information

Principal Investigator (PI)/Study Chair (SC) Name:		Academic Degrees:	
Board Certifications:			
Is there a Co-PI or Co-Study Chair?			
<input type="checkbox"/> No.			
<input type="checkbox"/> Yes. Name:		Site:	
<i>Note: If there is a Co-PI or Co-Study Chair, he or she must complete VA Central IRB Form 108a, Co-PI/SC New Project Application Supplement. This should be signed by the required officials at the Co-PI/SC's site and submitted as an attachment to this application.</i>			
Employment Status: (Check all that apply)			
<input type="checkbox"/> VA Employee (Indicate VA percentage of time in 8ths _____)			
<input type="checkbox"/> VA WOC (Without Compensation)			
<input type="checkbox"/> IPA (Intergovernmental Personnel Act)			
<input type="checkbox"/> Other (Specify) _____			
VA Facility Name:			
VA Station Number:		Phone:	
VA Facility Address:		Fax:	
		E-mail:	
Name of Project Coordinator:		Phone:	
FAX:		E-mail:	
1. Describe your qualifications to do the research detailed in this project and attach a copy of your biosketch (Merit Review or NIH Format):			
2. Indicate below how many of the following you currently oversee as a PI/SC:			
_____ Open Research Projects _____ Project Team Members (Project Coordinator, Statistician, etc.)			
_____ Participating Sites _____ Approximate Number of Active Project Participants			
3. Complete the following regarding your training and Conflict of Interest information:			
a. Date of VA Human Participant Protection/Good Clinical Practice Education:			
b. Has your participation in this project been reviewed by your local Conflict of Interest or in accordance with your local conflict of interest policies and procedures?			
<input type="checkbox"/> Yes. The findings of my local Conflict of Interest Committee or other local Conflict of Interest review are attached.			
<input type="checkbox"/> Review is pending. Determination will be forwarded upon completion of review. I understand no final decision regarding approval can be made by the VA Central IRB until the local Conflict of Interest determinations have been received and reviewed.			

4. Does this project involve a Coordinating Center? ☐ Yes ☐ No

If yes, please provide the name of the Coordinating Center and contact information below.

Name of Coordinating Center:

Contact Name (Program Manager or other POC):

Phone Number:

E-mail Address:

Note: A VA Central IRB Form 108b, Cooperative Studies Program (CSP) Coordinating Center PI/SC New Project Application must also be completed by Coordinating Center personnel and attached as a supplement to this application.

5. Is a separate Local Site Investigator Application going to be submitted from the PI/SC site?

A separate Local Site Investigator Application will need to be submitted if potential participants in the study will be recruited at the site and/or participating in the study using site resources. Please contact the VA Central IRB Administration Office if you have further questions concerning whether a separate Local Site Investigator Application is needed.

☐ Yes. Continue to Section 2. Information on other study team members from this site will and state and local laws will be included on the Local Site Investigator Application.

☐ No. Please complete the below information.

a. Please list project team members in the table below who will be involved in directing and/or conducting the project at this site. Submit a Conflict of Interest determination for all study members that will participate with 5% or more effort. Attach biosketches or CVs of all study team members who function in a scientific or medical capacity.

Note: Do not list CSP Coordinating Center personnel. If any CSP Personnel are also investigators, these should be listed on the VA Central IRB Form 108b.

Project Team Member	Degrees	5% or More Effort? Yes/No	Project Role	Access to Identifiable Participant Data? Yes/No	Date of Latest VA Human Subjects Protection Training

Note: Additional project members may be added by inserting more rows in the table. If some project members are unknown at this time, they can be added at a later date through submission of an amendment.

b. Are there any applicable state and local laws that differ from VA and other federal requirements concerning the conduct of human research (e.g., who may serve as a legally authorized representative?)

☐ Yes ☐ No

If yes, please describe:

Section 2: Project Overview

Please Note: For VA Central IRB review, your protocol must contain all information described in Sections 2 through 11 of this Application. In most cases, the protocol submitted for Merit Review will require substantial modifications to meet this requirement.

1. What type of protocol is this? (Please check one)

☐ CSP ☐ Clinical Science ☐ HSR&D ☐ Rehab ☐ VHA Central Office
☐ Other (Specify):

2. Give a brief **non-technical** summary of the project in terms that would be understandable to non-medical personnel. (Please limit to a maximum of 500 words as counted by your spell checker.)

3. Is this a clinical trial? ☐ Yes ☐ No

If yes, what type? (Check all that apply)

☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV

4. What is the purpose of the project?

5. What are the research questions or hypotheses? (Please cite scientific or scholarly rationale.)

6. What research methods will be used in the project? (Check all that apply)

<input type="checkbox"/> Surveys/Questionnaires	<input type="checkbox"/> Interviews	<input type="checkbox"/> Audio Taping
<input type="checkbox"/> Behavioral Observations	<input type="checkbox"/> Chart Reviews	<input type="checkbox"/> Video Taping
<input type="checkbox"/> Focus Groups	<input type="checkbox"/> Randomization	<input type="checkbox"/> Double-Blind
<input type="checkbox"/> Control Group	<input type="checkbox"/> Placebo	<input type="checkbox"/> Withhold/Delay Treatment
<input type="checkbox"/> Specimen Collection	<input type="checkbox"/> Deception	<input type="checkbox"/> Other (Specify:)

7. Describe the project design, methods of statistical analysis, sample size, and power analysis as applicable.

8. What participant procedures/interventions are required solely for project-required purposes and what procedure are already being used for diagnostic and treatment purposes? (Ex: lab tests, radiographic procedures, etc.)

9. What is the importance of the knowledge this project is likely to generate?

10. For intervention projects, are there procedures for the orderly withdrawal or termination of participation in the project by the participants?

☐ Yes ☐ No ☐ Not Applicable

If yes, please briefly describe the procedures or, if not, explain why there is not need for established procedures. (If yes, these procedures also need to be described in the informed consent document.)

11. Does this project involve international research?

Section 3: Potential Risk/Benefit Analysis

1. What are the potential risks or harms for participants in this project?

Note: *Risks or harms can be physical, psychological, financial, social, or legal. They may involve breaches of confidentiality and privacy.*

2. What are the anticipated benefits, if any, to participants or to society from this project?

3. Please describe procedures or monitoring activities designed to minimize risk:

4. Will radioactive materials be administered to participants?

☐ Yes ☐ No

5. Will participants be exposed to ionizing radiation as a result of project activities?

☐ Yes ☐ No

6. Does this project include a data safety monitoring plan?

☐ Yes ☐ No

Note: *The VA Central IRB requires a data safety monitoring plan (DSMP) for all studies greater than minimal risk to be included as part of the project.*

If yes, please specify the details of the plan.

7. Will an independent Data Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC) be involved in the monitoring of this project?

☐ Yes ☐ No

If yes, please provide contact information for the DSMB or DMC or Coordinating Center Representative and attach a copy of the charter or provide a description of its responsibilities:

Name:

Phone Number:

Title:

E-mail:

☐ Check if charter is attached or will be provided.

8. How will you manage information from participating sites that might be relevant to participant protection (i.e., reports of problems, interim results)? Describe how that information will be conveyed to the VA Central IRB.

Section 4: Human Participant Information

1. What is your planned or targeted enrollment?

2. Please describe any inclusion or exclusion criteria and provide justification:

3. What populations will be targeted for recruitment as participants? *Check all that apply.*

Males	<input type="checkbox"/>
Females	<input type="checkbox"/>
Inpatients	<input type="checkbox"/>
Outpatients	<input type="checkbox"/>
VA Employees	<input type="checkbox"/>
Students	<input type="checkbox"/>
Non-English Speaking	<input type="checkbox"/>
Veteran Family members	<input type="checkbox"/>
Non-Veterans	<input type="checkbox"/>
Other (Specify)	<input type="checkbox"/>

If non-veterans is marked above, please explain why sufficient veterans are not available to participate in the project [VHA Handbook 1200.5, paragraph 16a]:

4. Does this project target a specific race or ethnic group as participants? ☐ Yes ☐ No

If yes, check all that apply.

Race	
American Indian or Alaskan Native	<input type="checkbox"/>
Asian	<input type="checkbox"/>
Black or African American	<input type="checkbox"/>
Native Hawaiian or other Pacific Islander	<input type="checkbox"/>
White	<input type="checkbox"/>
Other	<input type="checkbox"/>

Ethnicity	
Hispanic or Latino	<input type="checkbox"/>
Not Hispanic or Latino	<input type="checkbox"/>
Other	<input type="checkbox"/>

Why was this group(s) chosen?

5. What are the age ranges of participants? *If yes, check all that apply.*

Children (Under 18) Requires Waiver from CRADO	<input type="checkbox"/>
Young Adults (18-21)	<input type="checkbox"/>
Adults (22-65)	<input type="checkbox"/>
Seniors (Over 65)	<input type="checkbox"/>

6. Are there specific reasons why certain populations (i.e., age or ethnic groups) are excluded as participants? ☐ Yes ☐ No

If yes, please specify reasons:

7. Does the project require enrollment of the following populations or categories of participants?

	Yes	No
a. Employees or students	<input type="checkbox"/>	<input type="checkbox"/>
b. Individuals with impaired decision making capability	<input type="checkbox"/>	<input type="checkbox"/>
c. Pregnant women	<input type="checkbox"/>	<input type="checkbox"/>
d. Economically and/or educationally disadvantaged persons	<input type="checkbox"/>	<input type="checkbox"/>
e. Prisoners	<input type="checkbox"/>	<input type="checkbox"/>
f. Illiterate, limited, or no English language proficiency	<input type="checkbox"/>	<input type="checkbox"/>
g. Terminally ill patients	<input type="checkbox"/>	<input type="checkbox"/>

8. If applicable, what is the justification for including any of the above populations or categories of participants in the project?

9. If the project requires enrolling any of the above populations or categories of participants, please describe any project-specific measures or special considerations, steps, or safeguards to ensure that these populations or special classes are adequately protected. *(Also attach the applicable vulnerable population supplement, VA Central IRB Form series 110, if enrolling pregnant women, prisoners, children, or participants with impaired decision-making capability)*

Section 5: Informed Consent

1. Are you requesting a waiver or alteration of informed consent? *(Check all that apply)*

<input type="checkbox"/>	No
<input type="checkbox"/>	Yes (VA Central IRB Form 112a is attached)
<input type="checkbox"/>	Yes, for recruitment purposes only. (VA Central IRB Form 112a is attached)

2. Who will be authorized to provide documented informed consent? *(Check all that apply)*

<input type="checkbox"/>	Informed Consent will not be sought.
<input type="checkbox"/>	Written informed consent from participants (VA Form 10-1086 is attached).
<input type="checkbox"/>	Written informed consent from participants' legally authorized representatives (LAR) as required by VA policy and/or applicable state laws (VA Form 10-1086 is attached).
<input type="checkbox"/>	Request Waiver of Documentation of Informed Consent (VA Central IRB Form 112b is attached).

3. Do you have a plan for training Local Site Investigators on informed consent procedures?

☐ Yes ☐ No ☐ Not Applicable

If yes, please describe the training plan and if no, justify why not.

4. Is anyone on the PI/SC study team that is not going to be listed on a Local Site Application going to be involved in obtaining informed consent?

☐ Yes ☐ No

If yes, please indicate who will be obtaining informed consent:

5. Does the project propose the use of assent for participants unable to give informed consent?

☐ Yes ☐ No ☐ Not Applicable

If yes, please describe the process for obtaining assent:

6. How will the participant's privacy interests be protected?

7. How are participants to be protected against undue influence or coercion?

8. Indicate below what method was used to perform a readability evaluation of the written model informed consent form and the results.

Note: A model VA Form 10-3203, Consent for Use of Picture and/or Voice, must also be submitted when a video or audio recording of a research subject is made *and* documentation of the research subject's participation is included in the research subject's VHA health record.

Section 6: HIPAA Authorization for Project Participants

Please check all of the following that apply if Protected Health Information (PHI) will be used:

<input type="checkbox"/>	PHI is not being used. HIPAA authorization is not required.
<input type="checkbox"/>	A project specific participant HIPAA Authorization form is attached.
<input type="checkbox"/>	A request for a HIPAA Waiver of Individual Authorization (VA Central IRB Form 103) is attached.
<input type="checkbox"/>	A request for a HIPAA Waiver of Individual Authorization (VA Central IRB Form 103) for recruitment purposes only is attached. If checked, please provide justification:

Please note: The VA Central IRB does not accept informed consent documents that include the HIPAA authorization as part of the informed consent. It must be separate.

Section 7: Participant Recruitment Information

1. What are your recruitment strategies for participating sites (e.g., local clinics, general population, physician referrals, letter to prospective participants)?

(Note: VA policy prohibits "cold calls" to potential VA research participants.)

2. How will the recruitment strategies vary for participating sites?

3. Are any standard recruitment materials going to be made available to Local Participating Sites?

☐ Yes ☐ No

4. If yes, please indicate the types of materials to be used below and attach copies:

<input type="checkbox"/>	No advertisements will be used.
<input type="checkbox"/>	Fliers
<input type="checkbox"/>	Newspaper
<input type="checkbox"/>	Letters
<input type="checkbox"/>	Websites
<input type="checkbox"/>	Television
<input type="checkbox"/>	Radio
<input type="checkbox"/>	Video <i>(A script may be provided)</i>
<input type="checkbox"/>	Audio <i>(A script may be provided)</i>
<input type="checkbox"/>	Other <i>(Please specify, i.e., physician referrals)</i>

Note: All recruitment materials must be reviewed and approved by the VA Central IRB prior to being used as part of any recruitment activities.

Section 8: Payment to Participants

1. Please indicate the method of payment and substantiate the reason for payment in accordance with paragraph 12 of VHA Handbook 1200.5.

Please note: The method and relative amounts (e.g., mileage reimbursement) of payment must be the same at all participating sites whenever possible. Local Site Investigators must provide justification to the VA Central IRB for differences in method and/or relative amounts.

No Participant Payments	<input type="checkbox"/>
Travel and Parking	<input type="checkbox"/>
Cash or Check	<input type="checkbox"/> Amount per visit: Total amount:
Gift Cards	<input type="checkbox"/> Amount per visit: Total amount:
Other <i>(Specify, i.e., Meal vouchers:</i>	<input type="checkbox"/> Specify:

Provide justification for payment type and amount:

2. If participants are to be paid, specify when payment will be rendered or describe the payment schedule.

Section 9: Biological Specimens

1. If biological specimens will be used in this protocol, please list below the types of specimens. ☐ Not Applicable. Skip to Section 10.

2. Will biological specimens be collected for research purposes only?

- ☐ No
☐ Yes

3. Will biological specimens collected for clinical purposes be used in this protocol?

- ☐ No
☐ Yes

4. If biological specimens are used in this protocol, please respond to the following questions by checking the appropriate box:

	Yes	No	N/A
a. Does the project involve genetic testing?	<input type="checkbox"/>	<input type="checkbox"/>	
b. Will specimens be kept for future, unspecified use?	<input type="checkbox"/>	<input type="checkbox"/>	
c. Will samples be made anonymous to maintain confidentiality? <i>Note: Coding data is not considered making it anonymous.</i>	<input type="checkbox"/>	<input type="checkbox"/>	
d. Will specimens be destroyed after the project-specific use is completed?	<input type="checkbox"/>	<input type="checkbox"/>	
e. Will specimens be sold in the future?	<input type="checkbox"/>	<input type="checkbox"/>	
f. Will donors be paid for their specimens now or in the future?	<input type="checkbox"/>	<input type="checkbox"/>	
g. Will donors be informed of the results of the specimen testing?	<input type="checkbox"/>	<input type="checkbox"/>	
h. Are there any implications for family members based on specimen testing results? (If yes, they may be participants.)	<input type="checkbox"/>	<input type="checkbox"/>	
i. Will donors be informed of results obtained from their DNA?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. Will specimens be de-identified?

- ☐ Yes ☐ No

If yes, please describe the procedures you will use, to include at what point in the process will the specimens be de-identified.

6. What measures will you take to minimize the potential for physical, psychological, financial, social, or legal harm from breaches of confidentiality and privacy resulting from unauthorized access to or loss of the specimens?

7. Will you bank collected tissue?

- ☐ Yes ☐ No

If yes, specify where you will bank the tissue and, if this is a non-VA site, indicate if the mandatory approval from ORD has been sought through submission of a tissue banking application (VA Form 10-0436). Attach a copy of the form if available.

8. How will destruction of samples, to include those stored in a tissue bank, be substantiated?

Section 10: Privacy and Confidentiality

1. What type of data will be received by the Principal Investigator/Study Chair?

Check all that apply.

- ☐ De-identified – Data does not contain any identifiers that could link the data to a specific participant. *(See VHA Handbook 1605.01, Appendix B, para 2b, for a list of identifiers that must be removed before data can be considered de-identified. Data must be de-identified in accordance with HIPAA and Common Rule criteria. Scrambling of names and social security numbers is not considered de-identified information.)*
- ☐ Identified – Data contains direct identifiers sufficient to identify participants as indicated in VHA Handbook 1605.01, Appendix B, para 2b.
- ☐ Coded – Data linked to a specific subject by a code rather than a direct identifier. While the data may contain some protected health information only someone possessing the code can link the data to a particular participant.

If you checked coded, please specify who will maintain the link or code and who will have access to the link or code:

2. Will Protected Health Information (PHI) be obtained directly from project participants?

- ☐ Yes ☐ No

If yes, describe the PHI obtained in terms of specific data elements/identifiers (e.g., name, address, phone numbers)

3. Does the project require the use of existing PHI from a database, medical records, or research records?

- ☐ Yes ☐ No

If yes, specify the source of the existing PHI and the specific data elements/identifiers (e.g., name, address, phone numbers).

4. Will participants be contacted from existing PHI?

- ☐ Yes ☐ No

If yes, please specify how you will contact the participants:

5. Who will have access to the data? (Specify approximate number of personnel and their job categories, i.e., Co-investigators, Nurse Coordinators, etc.)

6. How will data be protected during transmission?

7. How will project research data be stored?

Note: If data will reside on a non-VA server or non-VA equipment, please specify above that The server is certified and accredited as required by the Federal Information Security Management Act of 2002 (FISMA) and that you have obtained the required permissions for use of a non-VA server. See your Information Security Officer (ISO)

8. How long will the research data be stored?
9. Describe how the data will be destroyed once the maximum retention period or the period specified above, if longer, is reached?

Note: Please include in your plan that the ISO and Privacy Officer will be notified within one hour of the improper use or disclosure, as well as any other local policies.

10. What is your plan for protecting project research data from improper use or disclosure?
11. Have you applied or do you plan to apply for a Certificate of Confidentiality?

☐ Yes ☐ No *If yes, you need to include this fact in the informed consent form if applicable.*

A Certificate of Confidentiality helps investigators protect the privacy of human research participants enrolled in biomedical, behavioral, clinical and other forms of sensitive research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant. For more information on Certificate of Confidentiality go to: <http://grants.nih.gov/grants/policy/coc/>.

Section 11: FDA-Regulated and Other Products

1. Does the project require use of FDA-regulated drugs, biologics, or devices?
- ☐ Yes ☐ No (Skip to Section 12)
2. Does the project involve an Investigational New Drug Application (IND) or Investigational New Device Exemption (IDE)?
- ☐ Yes ☐ No
- If yes, please complete the following:
- a. Indicate the name of the person or organization holding the IND or IDE
- b. Is there a plan for on-site data monitoring?
- ☐ Yes ☐ No
- If yes, specify who will conduct monitoring responsibilities and how often?
3. How will FDA-regulated products used in this study be dispensed and tracked to participating sites?

4. If using FDA-regulated drugs or biologics, please indicate use: Check here if N/A ☐.

<input type="checkbox"/>	Investigational or Unapproved Drug(s) or Biologics (Attach a copy of the FDA's acknowledgement letter stating that FDA received the IND application.)
<input type="checkbox"/>	Approved Drug(s) or Biologics For Approved Uses
<input type="checkbox"/>	Approved Drug(s) or Biologics for Unapproved Uses (Use will be inconsistent with product labeling or involves a new use, labeling, advertising change, or a change in dose, dosage form, administration schedule, or recipient)

5. List all drugs, biologics, or supplements to be used below. Check here if N/A ☐.

Generic Name	Trade Name	Manufacturer	Use Consistent with Product Labeling? Yes/No	IND Number if Applicable

Note: Add additional rows to table if necessary

a. Is an Investigator's brochure included with the application materials?

☐ Yes ☐ No If no, please indicate why?

b. For all approved drugs used for an unapproved use, describe the unapproved use. Check here if N/A ☐.

c. If an IND is not required, explain and/or provide sponsor or FDA documentation. Check here if N/A ☐.

6. If using FDA-regulated devices, please indicate use: Check here if N/A ☐.

<input type="checkbox"/>	Investigational or Unapproved Device(s)
<input type="checkbox"/>	Approved Device(s) for an Approved Use
<input type="checkbox"/>	Approved Device(s) for an Unapproved Use
<input type="checkbox"/>	Other Specify (e.g., humanitarian use device; 510k clearance)

7. List the FDA-regulated devices that will be used. Check here if N/A ☐.

Name	Manufacturer	Use Consistent with Product Labeling? Yes, No, or N/A	Significant Risk (SR) or Nonsignificant Risk (NSR), Unknown, or N/A	IDE Number if Applicable

a. Is manufacturer's device information included with the application materials?

☐ Yes ☐ No

b. If this is a non-significant risk device study, is documentation attached with the application materials explaining the manufacturer's or a sponsor's determination why the device is not a Significant Risk (SR) device ? (See 21 CFR 812)

☐ Yes ☐ No

c. If applying for an IDE, is a copy of the dated IDE application letter to the FDA attached?

☐ Yes ☐ No ☐ N/A

Section 12: Local Site Investigator and Local Participating Site Information:

What is the total number of Local Participating Sites?

Please list all Local Participating Sites and the Local Site Investigators, along with their contact information. Each Local Site Investigator must submit a Local Site Investigator Application (VA Central IRB Form 104) directly to the VA Central IRB.

As the Principal Investigator/Study Chair, it is your responsibility to ensure that the Local Site Investigators listed below are properly qualified to carry out all aspects of the research project that have been delegated to them. The Principal Investigator/Study Chair retains ultimate responsibility for the conduct of the project.

Note: Additional Local Participating Sites may be added in the future through submission of a project amendment and a Local Site Investigator Application to the VA Central IRB.

Local Site Investigator:	Local VA Facility:
Telephone:	VA Facility Address:
Email:	Line 1:
Fax:	Line 2:
	Line 3:

Copy and paste table as a "nested table" as many times as needed to list all Local Site Investigators.

Section 13: Principal Investigator/Study Chair Statement

1. As the Principal Investigator/Study Chair for this project, I acknowledge that I have the primary and ultimate responsibility for protecting the rights and welfare of research participants and that I understand the ethical principles of human participant protection and Good Clinical Practice. I have the competencies and the resources to conduct the research outlined in this application and I attest that the application is scientifically and ethically sound.

2. I also attest that all project team members will be trained on applicable project procedures and on all VA and other requirements pertaining to human participant protections as befits their roles, scope of practice, and responsibilities prior to participating in the project. I and my study team will conduct and oversee this project in accordance with all ethical standards required by the VA for the conduct of human subjects research.

3. I understand and accept that I am responsible for the following:

- Conducting the research in accordance with the VA Central IRB-approved project and all applicable VA and other requirements, including, but not limited to, human research requirements as described in VHA Handbook 1200.05, 38 CFR Part 16, FDA requirements, VA Central IRB requirements, and local policy and procedures.
- Submitting all amendments to the project or changes in the informed consent to the VA Central IRB for review and approval prior to initiation, except when necessary to eliminate immediate hazard to the participants. Any changes implemented as a result of an immediate hazard will be promptly reported to the VA Central IRB as a project deviation and an amendment submitted if determined necessary.
- Promptly reporting to the VA Central IRB any reportable activity as defined by VA and other requirements and by VA Central IRB policies and procedures.
- Conducting project monitoring and data safety monitoring activities (if applicable) as appropriate for the IRB-approved project.
- Providing continuing review and closure reports to the VA Central IRB in a timely manner and in accordance with the VA Central IRB policies and procedures, to include reports of any unanticipated problems involving risks to subject or others and/or serious and continuing noncompliance.
- Following applicable requirements (e.g., information security) relevant to the conduct of the VA Central IRB-approved project and the maintenance of research records in accordance with the VA Records Control Schedule.
- Ensuring research does not start until final approval has been received from the VA Central IRB and this facility's local Research and Development Office in accordance with local policies.

Principal Investigator/Study Chair Signature

Date

Section 14: Principal Investigator/Study Chair Supervisor
(Must be at least a Section or Department Chief)

I have reviewed this application as completed by the PI/SC, who is under my supervision. I approve the conduct of the research by the PI/SC, to include the use of any time and resources within this department/section/Facility, as specified in this application.

Supervisor

Date

Printed Name

Department/Section/Facility

Section 15: Associate Chief of Staff for Research and Development (ACOS/R&D) at PI/SC Local Facility

Note: If the ACOS/R&D is the PI/SC, the Facility's Chief of Staff must complete this Section.

As the Associate Chief of Staff for Research and Development or Chief of Staff at **(Name of Local Facility)**, I have reviewed this project and the Principal Investigator/Study Chair's qualifications and I certify the following:

- The Principal Investigator/Study Chair and, if applicable, the rest of the project team from this facility have the experience and training needed to conduct this project. All members of the project team have been appropriately credentialed, privileged, have an approved scope of practice, and have completed all required VA training in the protection of human participants and Good Clinical Practice.
- This facility has reviewed or is in the process of reviewing any potential conflicts of interest the Principal Investigator/Study Chair and any of the project team members may have in accordance with our local policies and procedures. A summary of the determinations made and any management plans is either attached to this application or will be forwarded separately for review by the VA Central IRB.
- This facility, the Principal Investigator/Study Chair, and the local project team have the resources to support the functions and operations of the project as detailed.
- This project will not begin at this facility until the PI/SC has received written approval to initiate the study in accordance with VHA Handbook 1200.01.

Please check one of the boxes below:

This facility will also serve as a participating site for this project and will also be submitting a separate Local Site Investigator Application (VA Central IRB Form 104) upon approval of this Principal Investigator/Study Chair New Project Application (VA Central IRB Form 108).

☐ Yes ☐ No

ACOS/R&D or Chief of Staff Signature

Date

ACOS/R&D or Chief of Staff Printed Name

Phone Number: _____

E-mail Address: _____

Local Site Investigator Application



VA Facility Name:

Please check to indicate application status:

Local Site Investigator Name:

☐ **Initial**

☐ **Revised
Version #:**

Application Instructions

Date:

- The Local Site Investigator (LSI), the LSI's supervisor, and the ACOS/R&D, or Chief of Staff if the ACOS/R&D, is the LSI, for a participating site must complete this form.
- Submit this entire application in **two** forms: (1) a signed hard copy and (2) an electronic copy sent by encrypted e-mail.
- Each section must contain a response. Please ensure all responses are consistent with the approved funded project, the Principal Investigator (PI)/Study Chair(SC) New Project Application, and model informed consent form (if applicable).
- Other documents associated with this application as checked below should also be submitted electronically. Documents can be submitted in PDF or Microsoft Word format with the exception of the informed consent document. This document must be submitted in Microsoft Word. Please ensure the file name includes the name of the document, site, and date (e.g., 104.site.date)

Contents of Application Package

The following documents are mandatory for all studies. Please check to indicate they are included:

- ☐ Local Site Investigator Application (VA Central IRB Form 104)
- ☐ Local Site Biosketches or CVs of Applicable Study Team Members (Merit Review or NIH Format)
- ☐ Local Study Team Conflict of Interest Determinations

Please include the below documents if applicable to the study. If the documents have been modified from the model documents provided by the PI/SC, other than inserting name of facility, local investigator names, and other contact information, please use the Microsoft Word track changes function to indicate modifications. Submit both tracked and untracked versions of the documents if such changes were made.

- ☐ VA Research Consent Form (VA Form 10-1086)
- ☐ Local HIPAA Authorization form
- ☐ Local Recruitment Materials
- ☐ Local Participant Study Instructions
- ☐ Local Versions of Questionnaires or Surveys
- ☐ Local Scripts
- ☐ VA Investigational Drug Information Record (VA Form 10-9012)
- ☐ Consent for Use of Picture and/or Voice (VA Form 10-3203) (*Only to be used if the form will be part of the participant's VA medical record.*)

Please list below any other documentation included in this application (e.g., results of review by other local committees.)

Submission Instructions

1. Please review your entire application prior to submission and ensure the following:

- All three required signatures have been obtained. For revisions, only the signature of the LSI is required. Ensure you include the version number and date for all revisions.
- The attachments match with what you have indicated on the preceding page
- Unnecessary page breaks have been removed and any formatting errors have been corrected
- All sections of the application have been completed or marked "Not Applicable."

2. Please contact your PI/SC Study Team for submission instructions. All Local Site Applications are to be submitted to the PI/SC Study Team. They will then in turn forward all Local Site Investigator Applications to the VA Central IRB Administration Office.

Note: For CSP studies, all submissions must be submitted through or endorsed by the applicable CSP Coordinating Center.

For any other questions, please contact the VA Central IRB staff by e-mail at va.central.irb@va.gov or at the following toll-free number: 877-254-3130.

LOCAL SITE INVESTIGATOR APPLICATION

PROTOCOL TITLE:

Section 1: Local Site Investigator General Information

Local Site Investigator (LSI) Name:

Academic Degrees:

Board Certifications:

Employment Status: *(Check all that apply)*

- ☐ VA Employee (Indicate VA percentage of time in 8ths _____)
☐ VA WOC (Without Compensation)
☐ IPA (Intergovernmental Personnel Act)
☐ Other (Specify) _____

VA Facility Name:

VA Station Number:

Phone:

VA Facility Address:

Fax:

E-mail:

- 1. Describe your qualifications to do the research detailed in this project and attach a copy of your biosketch (Merit Review or NIH format). Be specific in regards to your research experience.**

Note: If you do not have any prior research experience, please indicate what provisions are being made to provide oversight or mentoring

- 2. Indicate below how many of the following you currently supervise as a PI, Study Chair, or LSI (excluding this current application):**

_____ Open Research Projects
_____ Participating Sites

_____ Project Team Members
_____ Approximate Number of Active Project Participants

- 3. Please list project team members in the table below who will be involved in directing and/or conducting the project at this site. Attach a biosketch or CV of team members who will function in a medical or scientific capacity and Conflict of Interest Determination for all team members who will be expending 5% or more effort on this project.**

Project Team Member	Degrees	5% or More Effort? Yes/No	Project Role (<i>Specify or use project role key found in instructions for completing form</i>)	Access to Identifiable Participant Data? Yes/No	Date of Latest VA Human Subjects Protection Training

Note: Additional project members may be added by inserting more rows in the table. If some project members are unknown at this time, they can be added at a later date through submission of an amendment.

4. Has your participation in this project and that of your project team been reviewed by your local Conflict of Interest Committee or in accordance with your local conflict of interest policies and procedures?

- ☐ Yes. The determinations of my local Conflict of Interest Committee or other local Conflict of Interest review are attached.
- ☐ Review is pending. Determinations will be forwarded upon completion of review. I understand no final decision regarding approval of this project can be made by the VA Central IRB until the local Conflict of Interest Committee determinations have been received and reviewed.

Section 2: Local Participating Site Overview

1. Where will the research project be conducted? (Check all that apply)

- ☐ VA Inpatient Setting
☐ VA Outpatient Clinic
☐ VA Clinician Office
☐ VA Laboratories
☐ Participant Homes
☐ Affiliate Location
☐ Other (Specify):

If research is conducted at affiliate location, please specify where and how much of the project will be conducted at that location. Check ☐ N/A if not applicable.

2. What resources are available at your facility to treat emergencies resulting from project-related procedures, as well as any non-emergency or psychological referrals that may be required? (Check all that apply)

- ☐ Basic Life Support (BLS) trained personnel
☐ Advanced Cardiac Life Support (ACLS) trained personnel and crash cart
☐ Emergency drugs and supplies to stabilize participant until emergency personnel arrive
☐ Emergency response team within facility
☐ 911 or other emergency response number
☐ Psychological counseling
☐ N/A
☐ Other Please explain:

If not all resources required to treat emergencies resulting from project-related procedures, as well as non-emergency or psychological referrals that may be required, are available at your facility, specify below your plan to handle emergencies requiring these resources.

3. If the project is not conducted at a medical facility, what medical facility and/or services will you use in an emergency? ☐ N/A

How much time does it take to get to the above-named medical facility from where the project is to be conducted?

4. Are there applicable state and local laws that differ from VA and other federal requirements concerning the conduct of research activities (e.g., who may serve as a legally authorized representative)? *(Check with your local Research Office and or see instructions for completing this form)*
- ☐ No
☐ Yes; please explain:
5. Are there any cultural, ethnic, religious, or other special characteristics of the community, or local issues that the VA Central IRB needs to consider in its review of the project?
- ☐ No
☐ Yes; please explain:
6. Does this project require review by another local committee? *(e.g., Recombinant DNA Advisory Committee, Scientific Review Subcommittee, Radiation Safety Committee, Biosafety Committee)*
- ☐ No
☐ Yes. Please specify committees:
- If yes, please check one of the following:
- ☐ Results of committees listed above are attached
☐ Other committee reviews are still pending and are expected to be complete by:
(Indicate date when results will be available)

Section 3: Local Site Potential Risk/Benefit Analysis

1. Are there any additional risks to participants in this project at your site than what was described in the PI/SC Application? *(Note: Risks or harms can be physical, psychological, financial, social, or legal. They may also involve breaches of confidentiality and privacy.)*
- ☐ No
☐ Yes; please explain:
2. Are there any differences in anticipated benefits to participants or society at your site from what was described in the PI/SC Application?
- ☐ No
☐ Yes; please explain:
3. What is your plan for identifying any problems that arise during the conduct of this project at your site? *(e.g., How will you identify adverse events?)*
4. How will you convey information, such as serious adverse events, to the Principal Investigator/Study Chair and/or to the VA Central IRB? *(e.g., encrypted e-mail, secure fax)*
5. If the VA Central IRB determined during its review of the PI/SC New Study Application that the medical record must be flagged, how this is done at your site? ☐ N/A

Section 4: Local Site Human Participant Information

1. What is your planned or targeted enrollment at this site and what is your expected accrual rate (e.g., number per month)?
2. What populations at your site will be targeted for recruitment as participants? *Check all that apply.*

Males	<input type="checkbox"/>
Females	<input type="checkbox"/>
Inpatients	<input type="checkbox"/>
Outpatients	<input type="checkbox"/>
VA Employees	<input type="checkbox"/>
Students	<input type="checkbox"/>
Non-English Speaking	<input type="checkbox"/>
Veteran Family members	<input type="checkbox"/>
Non-Veterans	<input type="checkbox"/>
Other (Specify)	<input type="checkbox"/>

If non-veterans is marked above, please explain why sufficient veterans are not available at your site to participate in the project: [VHA Handbook 1200.5, paragraph 16a]

3. Will you target a specific race or ethnic group as participants? ☐ Yes ☐ No

If yes, check all that apply.

Race		Ethnicity	
American Indian or Alaskan Native	<input type="checkbox"/>	Hispanic or Latino	<input type="checkbox"/>
Asian	<input type="checkbox"/>	Not Hispanic or Latino	<input type="checkbox"/>
Black or African American	<input type="checkbox"/>		
Native Hawaiian or other Pacific Islander	<input type="checkbox"/>		
White	<input type="checkbox"/>		

4. What are the age ranges of participants? *Check all that apply.*

Children	<input type="checkbox"/>	*If checked, see below.
Young Adults (18-21)	<input type="checkbox"/>	
Adults (22-65)	<input type="checkbox"/>	
Seniors (Over 65)	<input type="checkbox"/>	

*A waiver from the Chief Research and Development Officer (CRADO) is required. (See VHA Handbook 1200.5) Please also answer the following questions below:

*What is the legal age for an adult in your local jurisdiction: _____

*Does your study include emancipated minors and if so, what is the definition of an emancipated minor in your local jurisdiction:

5. Do you plan to enroll any of the following populations or categories of participants at your site?

	Yes	No
a. Employees or students	<input type="checkbox"/>	<input type="checkbox"/>
b. Individuals with impaired decision making capability	<input type="checkbox"/>	<input type="checkbox"/>
c. Pregnant women	<input type="checkbox"/>	<input type="checkbox"/>
d. Economically and/or educationally disadvantaged persons	<input type="checkbox"/>	<input type="checkbox"/>
e. Patients for whom you currently provide medical care	<input type="checkbox"/>	<input type="checkbox"/>
f. Prisoners	<input type="checkbox"/>	<input type="checkbox"/>
g. Illiterate, limited, or no English language proficiency	<input type="checkbox"/>	<input type="checkbox"/>
h. Terminally ill patients	<input type="checkbox"/>	<input type="checkbox"/>

6. If you answer yes to any of the above populations or categories of participants, please describe any site-specific measures or special considerations, steps, or safeguards to ensure that these populations or special classes are adequately protected if different from those in the PI/SC Application or project. (See VHA Handbook 1200.5)

☐ No difference from PI Application or Not Applicable.

Section 5: Local Site Informed Consent

1. Will you be obtaining informed consent at this site?

☐ Yes ☐ No If no, please skip to Section 6.

2. Who will conduct the consent discussion with the local site participants? (Check all that apply)

- ☐ Local Site Investigator
☐ Local Sub/Co-investigator
☐ Local Research Project Team Member (Specify who: _____)
☐ Other: Please explain:

3. Where will the informed consent process at this site take place? (Check all that apply)

- ☐ N/A
☐ In a private room
☐ In a waiting room
☐ In an open ward
☐ In a group setting
☐ Over the phone
☐ Other: Please explain:

4. How will the participant's privacy interests be protected?

5. How will you be sure there is sufficient opportunity or time for the participants to read the informed consent and consider whether or not to participate before signing? (Check all that apply)

- ☐ Participants will be allowed to take the unsigned consent form home for consideration prior to signing it.
☐ Participants will be allowed a waiting period of _____ (e.g., number of hour/days) to consider their decision.
☐ Other Please explain:

6. Are there any differences in the steps taken at your site to minimize the possibility of coercion or undue influence from those described in the PI/SC Application?

- ☐ No
☐ Yes; please explain:

7. Will you or a member of your research team be obtaining informed consent from someone other than the participant?

- ☐ No
☐ Yes

If yes, how will you determine which individuals meet the criteria for being a legally authorized representative (LAR) under VA requirements or applicable state laws?

- ☐ Request documentation of authorization.
☐ Obtain verbal confirmation from the LAR.
☐ Other *Please explain:*

What is the definition of a LAR for your local jurisdiction:

8. Will you or a member of your research team be obtaining assent from participants who are unable to give informed consent (e.g., participants with impaired decision making capacity)?

- ☐ N/A
☐ No
☐ Yes

If you will not be obtaining assent from participants who are unable to give informed consent, please explain why not?

9. If some or all participants at this site have impaired decision making ability, how will their capacity to consent be determined? (*See instructions for completing form for further guidance.*) Check here if N/A ☐.

10. What is the language of the participants (or parents or LAR as applicable) you plan to enroll at this site?

- ☐ English
☐ Spanish. If your VA Facility has a large Spanish-speaking population of veterans, and you do not plan to recruit Spanish-speaking participants, please provide justification:
☐ Other:

11. If you are enrolling non-English speaking participants (or obtaining consent from non-English speaking parents or LARs), what is your plan for conducting the consent discussion in the language understandable to the participant, and for ongoing communication with the participant throughout the project and in case of emergency if applicable:

- ☐ N/A
☐ At least one member of the project team is fluent in the language that will be used for communication, and that staff member(s) will be available during emergencies
☐ The project team has 24-hour access to a translation service with sufficient medical expertise to discuss the research in this project.
☐ Other *Please explain:*

12. Besides the Local Site Investigator and site-specific points of contact information, have you further modified the model informed consent document(s) provided by the Principal Investigator/Study Chair?

☐ Yes ☐ No

If yes, please provide justification for the changes:

Reminder: Please use the Microsoft Word track changes function to indicate modifications in the model informed consent document provided by the PI/SC. Submit BOTH tracked and untracked versions of the documents.

Section 6: Type of HIPAA Research Subject Authorization Being Requested at Local Site

Have you made any modifications to the model HIPAA authorization documents provided by the Principal Investigator/Study Chair?

☐ Yes ☐ No ☐ N/A

If yes, please provide justification and provide copies of the modified documents:

Section 7: Local Site Participant Recruitment Information

1. Who will be primarily responsible for recruiting potential participants at this site?

2. How will initial contact with the participant be made? (e.g. local clinics, general populations, physician referrals, letters to prospective participants – Note: VA policy prohibits “cold calls” to potential VA research participants.)

3. Will you be using any of the following methods to recruit participants?

(Please check all that apply.)

- ☐ N/A
☐ Database for which participants have given prior permission to be contacted for research
☐ Personal contact with patients or students over whom you have direct/indirect oversight
☐ Referrals

4. Please indicate below the following types of recruitment materials that will be used at this site?

<input type="checkbox"/>	No Advertisements will be used.
<input type="checkbox"/>	Fliers
<input type="checkbox"/>	Newspaper
<input type="checkbox"/>	Letters
<input type="checkbox"/>	Websites
<input type="checkbox"/>	Television
<input type="checkbox"/>	Radio
<input type="checkbox"/>	Video
<input type="checkbox"/>	Audio
<input type="checkbox"/>	Customer Surveys
<input type="checkbox"/>	Other (Please specify, i.e., physician referrals)

Please note that drafts of advertisements and scripts of audio and video materials may be provided for review. However, final versions of all recruitment materials must be reviewed and approved by the VA Central IRB prior to being used as part of any recruitment activities.

- 5. If standard recruitment materials were provided by the Principal Investigator/Study Chair, have you made any changes to those materials other than local site name or Local Site Investigator contact information?**

☐ Yes ☐ No ☐ N/A

If yes, please explain:

- 6. Will Protected Health Information (PHI) be obtained directly from participants at this site?**

☐ Yes ☐ No

If yes, describe the PHI obtained in terms of specific data elements/identifies (*e.g., name, address, phone numbers*)

- 7. Will you be contacting participants from existing PHI?**

☐ Yes ☐ No

If yes, specify the source of the existing PHI.

Section 8: Local Site Payment to Participants

- 1. Does your payment plan (methods or relative amounts of payment) differ that than described in the PI/SC Application?**

- ☐ No. Continue to Section 8.
☐ Yes; please explain and complete the table below:

No Participant Payments	<input type="checkbox"/>
Travel and Parking	<input type="checkbox"/>
Cash or Check	<input type="checkbox"/> Amount per visit: Total amount:
Gift Cards	<input type="checkbox"/> Amount per visit: Total amount:
Other (<i>Specify, i.e., Meal vouchers:</i>)	<input type="checkbox"/> Specify:

- 2. If you answered yes, please indicate method and timing of payments (*e.g., by check two weeks after initial visit and every three months thereafter upon certification of completion of visits*).**

Section 9: Local Site Biological Specimens

1. If biological specimens will be used in this protocol, please list the types of specimens below:

☐ Not Applicable. Skip to Section 10.

2. Will biological specimens be collected for research purposes only?

☐ Yes
☐ No

3. Will biological specimens collected for clinical purposes be used in this protocol?

☐ Yes
☐ No

4. Will specimens be de-identified?

☐ Yes
☐ No

If yes, please describe below the procedures you will use if different from those described in the PI/SC Application. ☐ N/A (Procedures are the same)

5. Are there any differences in the measures you will take to minimize the potential for physical, psychological, financial, social, or legal harm from breaches in confidentiality and privacy resulting from participating in this aspect of the research project than those described in the PI/SC Application?

☐ Yes
☐ No

6. Will you bank collected tissue?

☐ Yes
☐ No

If tissues are to be banked and the tissue banking procedures differ from those described in the project by the Principal Investigator/Study Chair, specify where the tissue is to be banked.

If this is a non-VA site, a tissue banking application (VA Form 10-0436) must be submitted to ORD and approved. Attach a copy of the form if available.

Section 10: Local Site Privacy and Confidentiality

PLEASE NOTE: This section must be individualized for your local site.
Do not cut and paste sections of the protocol to address the questions.

1. What type of data will be collected by the project team at this site?

- ☐ De-identified – Without any identifiers that could link the data to a specific participant
(Data must be de-identified in accordance with HIPAA and Common Rule criteria. Consult with your Privacy Officer if unsure whether data is de-identified.)
- ☐ Identified – Linked to a specific participant by personal identifiers sufficient to identify participants

2. Will the data be coded? (i.e., linked to a specific participant by personal identifiers sufficient to identify participants or by a unique code – coded data is not considered de-identified)

- ☐ No
☐ Yes

If yes, please specify who will maintain the link or code and all personnel who have access to it:

3. Are there any procedures concerning the collection of data which differ from those specified in the PI/SC Application?

- ☐ No
☐ Yes; please specify:

4. Will transmission of project research data from this site to the Principal Investigator/Study Chair or Coordinating Center differ from how it is described in the PI/SC Application?

- ☐ No
☐ Yes; please specify:

5. Will the storage of project research data at this site differ from how it is described in the PI/SC application? Please note: Records destruction must be in accordance with the VHA Records Control Schedule.

- ☐ No
☐ Yes; please specify:

Note: If data will reside on a non-VA server, please specify above that the server is certified and accredited as required by the Federal Information Security Management Act of 2002 (FISMA) and that the required permissions for use of a non-VA server have been obtained.

6. Will your plan for protecting project research data generated from this site differ from how it is described in the PI/SC application?

- ☐ No
☐ Yes; please specify:

Section 11: FDA-Regulated and Other Products Used at Local Site

1. Does the project require use of FDA-regulated drugs, biologics, devices, or other products at this site? *(Note: Include all drugs and devices required as part of the project or trial.)*

☐ Yes ☐ No (Skip to Section 12)

2. What are the FDA-regulated drugs, biologics, devices, or other products such as supplements, that will be evaluated and/or dispensed at this site? List below.

If a device(s) is used, who will have control and manage the device(s)?

3. How will FDA-regulated and other products used in this protocol be dispensed and tracked to participants at this site?

4. If using drugs, has the Pharmacy been contacted and agreed with the plan?

☐ Yes
☐ No

If no, please indicate why:

Note: For investigational drugs, attach a completed and signed local VA Form 10-9012, Investigational Drug Information Record for each drug, to be approved by the VA Central IRB.

Section 12: Local Site Investigator Statement

1. As the Local Site Investigator for this project, I attest to the following:

- I acknowledge that I have the primary and ultimate responsibility for protecting the rights and welfare of research participants at this site and that I understand the ethical principles of human participant protection and Good Clinical Practice. I and my study team will conduct and oversee this project in accordance with all ethical standards required by the VA for the conduct of human subjects research.
- I reviewed the project application as submitted by the Principal Investigator/Study Chair and have indicated on this application if I have made any changes in the model documents.
- I have adequate local resources and time to complete this project.
- All members of the local project team will be trained on applicable project procedures, to include informed consent procedures, and on all VA and other requirements pertaining to human participant protections as befits their roles and responsibilities as detailed in their scope of practice prior to participating in the project.
- The project team has access to a population that will allow recruitment of the required number of participants.
- Our local VA facility has adequate resources to support the conduct of this project, including medical and psychological resources that participants might require as a consequence of their participation in the project.

2. I accept that I have responsibility for the following:

- Conducting the project according to all applicable requirements, including but not limited to VHA Handbook 1200.05, 38 CFR 16, FDA requirements, VA Central IRB requirements, and local policy and procedures.
- Not make any changes to the protocol, without prior VA Central IRB approval, except to eliminate immediate hazards to participants.
- Promptly reporting to the VA Central IRB, the local Institutional Official, and Principal Investigator/Study Chair any reportable activity as defined by VA and other requirements, as well as VA Central IRB policies and procedures, to include reports of any unanticipated problems involving risks to subject or others and/or serious and continuing noncompliance.
- Cooperating with the Principal Investigator/Study Chair in the submission of all project amendments and continuing review reports.
- Following applicable requirements (e.g., information security) relevant to the conduct of the VA Central IRB-approved project and the maintenance of research records in accordance with the VA Records Control Schedule.

Local Site Investigator Signature

Date

Local Site Investigator Printed Name

Section 13: Local Site Investigator's Supervisor (Must be at least a Section or Department Chief)

I have reviewed this application as completed by the Local Site Investigator, who is under my supervision. I approve the conduct of the research by the Local Site Investigator, to include the use of any time and resources within this Department/Section/Facility, as specified in this application.

Supervisor

Date

Printed Name

Department/Section/Facility

Section 14: Review by Local Site Associate Chief of Staff for Research and Development (ACOS/R&D) at the Local Investigator's Site

Note: If the ACOS/R&D is the LSI, the Facility's Chief of Staff must complete this Section.

1. As the Associate Chief of Staff for Research and Development or Chief of Staff {Name of Local Facility}, I have reviewed this project, the local site project team qualifications, and site requirements. I have concluded that this facility is an acceptable site to conduct this project and I certify the following:

- The Local Site Investigator and the rest of the local site project team have the experience and training to conduct this research. All members of the project team have been appropriately credentialed, privileged, have an appropriate scope of practice, and have completed all required VA training in the protection of human participants and Good Clinical Practice.
- This facility has reviewed or is in the process of reviewing any potential conflicts of interest any of the project team members may have in accordance with our local policies and procedures. A summary of the determinations made and any management plans is either attached to this application or will be forwarded separately for review by the VA Central IRB.
- The local project team has access to a population that will allow recruitment of the required number of participants and the local project team has the time to complete the project.
- This project will not begin at this site until the LSI has received written approval to initiate the study in accordance with VHA Handbook 1200.01.
- This facility has adequate resources, including medical and psychological resources that participants might require as a consequence of their participation in the project, to support the functions of this site as detailed in the project.

2. I have considered whether or not there are state and local laws governing the proposed project. I have also considered whether there are any cultural, ethnic, religious, or special characteristics of the community, or other local issues that the VA Central IRB needs to consider in its review. I have the following comments regarding these local context issues: *(If none, so state)*

3. The Federalwide Assurance for our VA Facility is current and lists or will list the VA Central IRB as an IRB of Record for this facility. We have a current, approved Memorandum of Understanding (MOU) on file with the VHA Central Office Human Research Protections Program (HRPP) or will obtain one prior to this Local Site Investigator Application being considered by the VA Central IRB for approval.

ACOS/R&D or Chief of Staff Signature

Date

ACOS/R&D or Chief of Staff Printed Name

Phone Number: _____

E-mail Address: _____

Co-Principal Investigator/Study Chair New Project Application Supplement



Co-Principal Investigator/Study Chair Name:

VA Facility Name:

Check to indicate application status:

☐ Initial

☐ Revised

Version #:

Project Title:

Date:

Supplement Application and Submission Instructions

- The Co-Principal Investigator (PI)/Study Chair (SC) must use this form to submit as a supplement to the Principal Investigator/Study Chair New Project Application to the VA Central IRB. The Co-PI/SC's Supervisor and ACOS/R&D or Chief of Staff of the Co-PI/SC's site also must complete a portion of this form. For revised applications, only the signature of the PI/SC is required. Ensure the version number and date are included for all revisions.
- Upon completion of this form, it should be appended to the VA Central IRB Form, PI/SC New Project Application and submitted with the rest of the application package.

Section 1: Co-PI/Study Chair General Information

Co- Principal Investigator (PI)/Study Chair (SC) Name:

Academic Degrees:

Board Certifications:

Employment Status: *(Check all that apply)*

- ☐ VA Employee (Indicate VA percentage of time in 8ths _____)
- ☐ VA WOC (Without Compensation)
- ☐ IPA (Intergovernmental Personnel Act)
- ☐ Other (Specify) _____

VA Facility Name:

VA Station Number:

Phone:

VA Facility Address:

Fax:

E-mail:

Name of Project Coordinator:

Phone:

FAX:

E-mail:

1. Describe your qualifications to do the research detailed in this project and attach a copy of your biosketch (Merit Review or NIH Format):

2. Indicate below how many of the following you currently oversee as a PI/SC or Co-PI/SC:

_____ Open Research Projects _____ Project Team Members (*Project Coordinator, Statistician, etc.*)
_____ Participating Sites _____ Approximate Number of Active Project Participants

3. Complete the following regarding your training and Conflict of Interest information:

- a. Date of VA Human Participant Protection/Good Clinical Practice Education:
- b. Has your participation in this project been reviewed by your local Conflict of Interest or in accordance with your local conflict of interest policies and procedures?
- ☐ Yes. The findings of my local Conflict of Interest Committee or other local Conflict of Interest review are attached.
- ☐ Review is pending. Determination will be forwarded upon completion of review. I understand no final decision regarding approval can be made by the VA Central IRB until the local Conflict of Interest determinations have been received and reviewed.

4. Is the Co-PI from the same site as the PI? ☐ Yes ☐ No

If yes, skip to Section 2.

If no, please complete the remainder of this section.

5. Is a separate Local Site Investigator Application going to be submitted from this site? *A separate Local Site Investigator Application will need to be submitted if potential participants in the study will be recruited at the site and/or participating in the study using site resources. Please contact the VA Central IRB Administration Office if you have further questions concerning whether a separate Local Site Investigator Application is needed.*

- ☐ Yes. Continue to Section 2. Information on other study team members from this site will be included on the Local Site Investigator Application.
- ☐ No. Please complete the below information.

Please list project team members in the table below who will be involved in directing and/or conducting the project at this site. Submit a Conflict of Interest determination for all study members that will participate with 5% or more effort. Attach biosketches or CVs of all study team members who function in a scientific or medical role.

Project Team Member	Degrees	5% or More Effort? Yes/No	Project Role	Access to Identifiable Participant Data? Yes/No	Date of Latest VA Human Subjects Protection Training

Note: Additional project members may be added by inserting more rows in the table. If some project members are unknown at this time, they can be added at a later date through submission of an amendment or reported at continuing review as applicable.

Section 2: Co-Principal Investigator/Study Chair Statement

1. As a Co-Principal Investigator/Study Chair for this project, I acknowledge that I share primary and ultimate responsibility for protecting the rights and welfare of research participants with other Co-PI/SCs and that I understand the ethical principles of human participant protection and Good Clinical Practice. I have the competencies and resources adequate to conduct the research outlined in this application and I attest that the application is scientifically and ethically sound.

2. I attest that all project team members will be trained on applicable project procedures and on all VA and other requirements pertaining to human participant protections as befits their roles, scope of practice, and responsibilities prior to participating in the project. I and my study team will conduct and oversee this project in accordance with all ethical standards required by the VA for the conduct of human subjects research.

3. I understand and accept that I am responsible for the following:

- Conducting the research in accordance with the VA Central IRB-approved project and all applicable VA and other requirements, including, but not limited to, human research requirements as described in VHA Handbook 1200.05, 38 CFR Part 16, FDA requirements, VA Central IRB requirements, and local policy and procedures.
- Submitting all amendments to the project or changes in the informed consent to the VA Central IRB for review and approval prior to initiation, except when necessary to eliminate immediate hazard to the participants. Any changes implemented as a result of an immediate hazard will be promptly reported to the VA Central IRB as a project deviation and an amendment submitted if determined necessary.
- Promptly reporting to the VA Central IRB any reportable activity as defined by VA and other requirements and by VA Central IRB policies and procedures.
- Conducting project monitoring and data safety monitoring activities (if applicable) as appropriate for the IRB-approved project.
- Providing continuing review and closure reports to the VA Central IRB in a timely manner and in accordance with the VA Central IRB policies and procedures, to include reports of any unanticipated problems involving risks to subjects or others and /or serious and continuing noncompliance.
- Following applicable requirements (e.g., information security) relevant to the conduct of the VA Central IRB-approved project.
- Ensuring research does not start until final approval has been received from the VA Central IRB and this facility's local Research and Development Office in accordance with local policies

Co-Principal Investigator/Study Chair Signature

Date

**Section 3: Co-Principal Investigator/Study Chair Supervisor
(Must be at least a Section or Department Chief)**

I have reviewed this application as completed by the Co-PI/SC, who is under my supervision. I approve the conduct of the research by the Co-PI/SC, to include the use of any time and resources within this department/section/Facility, as specified in this application.

Supervisor

Date

Printed Name

Department/Section/Facility

**Section 4: Associate Chief of Staff for Research and Development (ACOS/R&D) at
Co-PI/SC Local Facility**

Note: If the ACOS/R&D is the Co-PI/SC, the Facility's Chief of Staff must complete this Section.

As the Associate Chief of Staff for Research and Development or Chief of Staff at **(Name of Local Facility)**, I have reviewed this project and the Co-Principal Investigator/Study Chair's qualifications and I certify the following:

- The Co-Principal Investigator/Study Chair and, if applicable, the rest of the project team from this facility have the experience and training needed to conduct this project. All members of the project team have been appropriately credentialed, privileged, and have completed all required VA training in the protection of human participants and Good Clinical Practice.
- This facility has reviewed or is in the process of reviewing any potential conflicts of interest the Co-Principal Investigator/Study Chair and any of the project team members may have in accordance with our local policies and procedures. A summary of the determinations made and any management plans is either attached to this application or will be forwarded separately for review by the VA Central IRB.
- This facility, the Co-Principal Investigator/Study Chair, and the local project team have the resources to support the functions and operations of the project as detailed.
- This project will not begin at this facility until the Co-PI/SC has received written approval to initiate the study in accordance with VHA Handbook 1200.01.

Please check one of the boxes below:

This facility will also serve as a participating site for this project and will also be submitting a separate Local Site Investigator Application (VA Central IRB Form 104) upon approval of the Principal Investigator/Study Chair New Project Application (VA Central IRB Form 108).

☐ Yes ☐ No

ACOS/R&D or Chief of Staff Signature

Date

ACOS/R&D or Chief of Staff Printed Name

Phone Number: _____

E-mail Address: _____

Request for Expedited Review of New Project



This form is used by the Principal Investigator to request an expedited review by the VA Central IRB of a new project.

Section 1: Project and Principal Investigator Information

Title of Project:	
Name of Principal Investigator (PI):	
PI Phone Number:	PI E-Mail Address:
Name of PI Facility:	
Mailing Address:	

Section II: Evaluation of Risk

All three boxes must be checked in order to proceed to Section III and request an expedited review.

If all three boxes are not checked, the project does not qualify for expedited review and this form does not need to be submitted with the PI New Project Application.

☐ The project presents no more than minimal risk to participants.

A project is minimal risk if the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (38 CFR 16.102(i)).

☐ The identification of participants or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

☐ The project is not classified.

Section III: Expedited Review Category

Please check one or more of the following categories to indicate the category under which this project qualifies for expedited review.

If the project does not fit into one of the below categories, it does not qualify for expedited review.

- ☐ **Category 1:** Clinical studies of drugs and medical devices only when one of the following conditions is met.
 - ☐ **1a:** An investigational device exemption application (21 CFR Part 812) is not required.
 - ☐ **1b:** The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- ☐ **Category 2:** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - ☐ **2a:** From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week.
 - ☐ **2b:** From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- ☐ **Category 3:** Prospective collection of biological specimens for research purposes by noninvasive means.
- ☐ **Category 4:** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.
- ☐ **Category 5:** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). This category also includes research involving materials that were previously collected for either non-research or research purposes, provided that any materials collected for research were not collected for the currently proposed research.
- ☐ **Category 6:** Collection from voice, video, digital or image recordings made for research purposes.
- ☐ **Category 7:** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Please provide a short justification for the assignment of the above category:

Section IV: Investigator Signature

I am requesting that this project be reviewed under the expedited review process. I believe this project meets the qualification for the designated expedited review category or categories indicated above.

Principal Investigator's Signature

Date

VA Central IRB Form 137 Updated March 17, 2010

[illegible][illegible]

[illegible]

Local Participating Site Tracking Log

Study:

PI Application

Site

IRB Num

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[illegible]

	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	100
0	0	1	4	9	16	25	36	49	64	81	100	121	144	169	196	225	256	289	324	361	400	441	484	529	576	625	676	729	784	841	900	961	1024	1089	1156	1225	1296	1369	1444	1521	1600	1681	1764	1849	1936	2025	2116	2209	2304	2401	2500	2601	2704	2809	2916	3025	3136	3249	3364	3481	3600	3721	3844	3969	4096	4225	4356	4489	4624	4761	4900	5041	5184	5329	5476	5625	5776	5929	6084	6241	6400	6561	6724	6889	7056	7225	7396	7569	7744	7921	8100	8281	8464	8649	8836	9025	9216	9409	9604	9801	10000

LSI Applications	Local R&D Approval from PI site must be received
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[illegible]

Site	Local Site	LSI	MOU/	30 Day LS	7-Day FU	30 Day LS	LSI APP

Trkg Num	FWA	Pkg Sent	Call/e-mail	Comm Rcvd	Recv'd	Review
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	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	
0	0	1	4	9	16	25	36	49	64	81	100	121	144	169	196	225	256	289	324	361	400	441	484	529	576	625	676	729	784	841	900	961	1024	1089	1156	1225	1296	1369	1444	1521	1600	1681	1764	1849	1936	2025	2116	2209	2304	2401	2500	2601	2704	2809	2916	3025	3136	3249	3364	3481	3600	3721	3844	3969	4096	4225	4356	4489	4624	4761	4900	5041	5184	5329	5476	5625	5776	5929	6084	6241	6400	6561	6724	6889	7056	7225	7396	7569	7744	7921	8100	8281	8464	8649	8836	9025	9216	9409	9604	9801	10000

[illegible][illegible][illegible]

Year	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040	2041	2042	2043	2044	2045	2046	2047	2048	2049	2050	2051	2052	2053	2054	2055	2056	2057	2058	2059	2060	2061	2062	2063	2064	2065	2066	2067	2068	2069	2070	2071	2072	2073	2074	2075	2076	2077	2078	2079	2080	2081	2082	2083	2084	2085	2086	2087	2088	2089	2090	2091	2092	2093	2094	2095	2096	2097	2098	2099	2100																																																																																																																																																																																												
Population (millions)	5.3	5.4	5.5	5.6	5.7	5.8	5.9	6.0	6.1	6.2	6.3	6.4	6.5	6.6	6.7	6.8	6.9	7.0	7.1	7.2	7.3	7.4	7.5	7.6	7.7	7.8	7.9	8.0	8.1	8.2	8.3	8.4	8.5	8.6	8.7	8.8	8.9	9.0	9.1	9.2	9.3	9.4	9.5	9.6	9.7	9.8	9.9	10.0	10.1	10.2	10.3	10.4	10.5	10.6	10.7	10.8	10.9	11.0	11.1	11.2	11.3	11.4	11.5	11.6	11.7	11.8	11.9	12.0	12.1	12.2	12.3	12.4	12.5	12.6	12.7	12.8	12.9	13.0	13.1	13.2	13.3	13.4	13.5	13.6	13.7	13.8	13.9	14.0	14.1	14.2	14.3	14.4	14.5	14.6	14.7	14.8	14.9	15.0	15.1	15.2	15.3	15.4	15.5	15.6	15.7	15.8	15.9	16.0	16.1	16.2	16.3	16.4	16.5	16.6	16.7	16.8	16.9	17.0	17.1	17.2	17.3	17.4	17.5	17.6	17.7	17.8	17.9	18.0	18.1	18.2	18.3	18.4	18.5	18.6	18.7	18.8	18.9	19.0	19.1	19.2	19.3	19.4	19.5	19.6	19.7	19.8	19.9	20.0	20.1	20.2	20.3	20.4	20.5	20.6	20.7	20.8	20.9	21.0	21.1	21.2	21.3	21.4	21.5	21.6	21.7	21.8	21.9	22.0	22.1	22.2	22.3	22.4	22.5	22.6	22.7	22.8	22.9	23.0	23.1	23.2	23.3	23.4	23.5	23.6	23.7	23.8	23.9	24.0	24.1	24.2	24.3	24.4	24.5	24.6	24.7	24.8	24.9	25.0	25.1	25.2	25.3	25.4	25.5	25.6	25.7	25.8	25.9	26.0	26.1	26.2	26.3	26.4	26.5	26.6	26.7	26.8	26.9	27.0	27.1	27.2	27.3	27.4	27.5	27.6	27.7	27.8	27.9	28.0	28.1	28.2	28.3	28.4	28.5	28.6	28.7	28.8	28.9	29.0	29.1	29.2	29.3	29.4	29.5	29.6	29.7	29.8	29.9	30.0	30.1	30.2	30.3	30.4	30.5	30.6	30.7	30.8	30.9	31.0	31.1	31.2	31.3	31.4	31.5	31.6	31.7	31.8	31.9	32.0	32.1	32.2	32.3	32.4	32.5	32.6	32.7	32.8	32.9	33.0	33.1	33.2	33.3	33.4	33.5	33.6	33.7	33.8	33.9	34.0	34.1	34.2	34.3	34.4	34.5	34.6	34.7	34.8	34.9	35.0	35.1

[illegible]

30-Day Comments

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Site	Board	Responsible
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Review?	Sent
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Rows are added as needed and columns expanded

Panes can be frozen as appropriate for ease in viewing on screen.

[illegible]

Administrative Pre-Screening Checklist for PI/SC New Project Applications



This form is used by VA Central IRB Administrative staff to perform an initial pre-screen of a PI/SC New Project Application

Section 1: Principal Investigator/Study Chair (PI/SC) and Project General Information

VA Central IRB Project Number Assigned:

Date Received:

Type of Review: ☐ Initial Review ☐ Re-Review

1. Project Title:
2. Name of Principal Investigator (PI):
3. Name of PI Site:
4. Is the PI Site a Local Participating Site: ☐ Yes ☐ No
5. Number of Local Participating Sites:
6. Is there a Co-PI? ☐ Yes ☐ No
If yes, does the application contain a completed VA Central IRB Form 108a? ☐ Yes ☐ No
7. Has the PI (Co-PI) provided their VA e-mail addresses? ☐ Yes ☐ No
8. Indicate the type of project: ☐ CSP ☐ Clinical Science
☐ HSR&D ☐ VHA Central Office
☐ Other (Specify):
9. LEIE Performed on PI/SC (and Co-PI/SC as applicable) on: Results:
10. Have all documents listed on the front of the VA Central IRB Form 108 been received?
☐ Yes ☐ No

List any missing required documents in Section 4 of this form.

Section 2: Issues That Must Be Addressed

1. Has the PI/SC (Co-PI/SC as applicable) completed VA Human Participant Protection/Good Clinical Practice Education within one year of project submission:
☐ No. Evidence of training completion within one year must be received prior to final approval of the project by the VA Central IRB. *Add to Section 5, Issue Requiring Resolution*
☐ Yes.
2. Has the local site identified a Conflict of Interest concerning the PI/SC (Co-PI/SC) and/or study team?
☐ No. File Local Conflict of Interest findings in study file and include as part of agenda package.
☐ Yes. Include as part of agenda package and if a potential COI was ruled out, ensure applicable documentation from the VA facility's Office of Regional Counsel ruling out the COI is provided.
☐ Pending. Local Conflict of Interest findings must be received and reviewed by the Board prior to approval of project. *Add this to Section 4, Missing Documents.*

3. Does the project involve a Coordinating Center? ☐ No ☐ Yes

If yes, the following questions must be answered.

- a. Does the Coordinating Center have an MOU/FWA on file?

- ☐ No. Immediately inform the VA Central IRB Administrator. *Add to Section 5.*
☐ Yes.

- b. For CSP projects, was the project submitted through the Coordinating Center POC?

- ☐ N/A
☐ Yes
☐ No. If no, contact the POC for the Coordinating Center and obtain verification in writing that the study version submitted is the one approved by the Coordinating Center.

4. Does the project appear to involve more than minimal risk?

- ☐ No.
☐ Yes. If yes, is a data safety monitoring plan included?
☐ No. *Add to Section 4.*
☐ Yes.

6. Does the project involve the use of a vulnerable population or a special class of participants?

- ☐ No.
☐ Yes. What vulnerable population is included? _____

A Vulnerable Population Supplement (VA Central IRB Form 110 series) must be included with application if project involves **prisoners, pregnant women, or participants with impaired decision making ability**. A Board member or an ad hoc advisor having experience with the vulnerable population must also be present at the meeting at which this project will be reviewed. Add to *Section 4* if one of these populations is to be enrolled and the applicable supplement is not attached.

7. How is informed consent going to be addressed? (*Check all that apply*)

- ☐ A waiver or alteration is being requested for the project.
☐ A waiver or alteration is being requested for recruitment purposes only.
☐ Written informed consent will be obtained from participants.
☐ Written informed consent will be obtained from participants' Legally Authorized Representative (LAR).
☐ Assent will be obtained from participants with impaired decision making capability.
☐ A waiver of documentation of informed consent is being requested.

Have all required documents been submitted?

- ☐ No. *List them in Section 4*
☐ Yes.

8. Has a readability evaluation been performed by the principal investigator on the informed consent document?

- ☐ No. Perform one using Word tools and indicate outcome. Result _____
☐ Yes. Result _____ *If results above 8th grade, list in Section 5.*

9. Are recruitment materials going to be provided to potential participants?

- ☐ No.
☐ Yes. Ensure copies of all recruitment materials are included as part of this application.
List missing materials in section 4.

10. Does the project involve the use of FDA-regulated drugs, biologics, or devices?

- ☐ No.
☐ Yes. If project involves drugs or devices for other than an approved use, ensure the investigator's drug brochure or manufacturer's device information is included in the application. *Any missing materials should be listed in Section 4.*

If yes, the following additional questions must be answered:

a. For investigational drugs, is a *Model VA Central IRB Form 10-9012* Investigational Drug Information Record included in the application?

- ☐ No. *List in Section 4.*
☐ Yes
☐ N/A

b. For investigational devices, has the investigator provided enough information about the device for the Board to make a SR/NSR determination?

- ☐ No. *List in Section 4.*
☐ Yes
☐ N/A

c. Has the IND or IDE been provided?

- ☐ No. *List in Section 4.*
☐ Yes
☐ N/A

If yes, validate and specify method and date of validation:

Method:

Date:

11. Is the application signed by the PI/SC, the PI/SC's supervisor, and the ACOS/R&D of the PI/SC Site?

- ☐ No. Immediately notify investigator of signature requirements. *Add to Section 5.*
☐ Yes.

Section 3: Informed Consent Administrative Review

Check here if N/A ☐

Required Elements	YES	NO	N/A
All of these elements must be present. If one or more are not present, contact the investigator and ask that a revised document be submitted. Add to Section 5.			
1. Does the informed consent contain the name of the project?	<input type="checkbox"/>	<input type="checkbox"/>	
2. Does the informed consent contain the name of the Principal Investigator?	<input type="checkbox"/>	<input type="checkbox"/>	
3. Is there a statement indicating that the project involves research?	<input type="checkbox"/>	<input type="checkbox"/>	
4. Is there an explanation of the purposes of the research?	<input type="checkbox"/>	<input type="checkbox"/>	
5. Is the duration of the participant's expected participation stated?	<input type="checkbox"/>	<input type="checkbox"/>	
6. Is there a detailed chronological description of the procedures to be followed?	<input type="checkbox"/>	<input type="checkbox"/>	

7. Are procedures that are being done solely for the purposes of the research identified as such?	<input type="checkbox"/>	<input type="checkbox"/>	
8. Are procedures which are experimental identified as such?	<input type="checkbox"/>	<input type="checkbox"/>	
9. Is the participant advised of any reasonably foreseeable risks or discomfort that may occur as a result of their participation?	<input type="checkbox"/>	<input type="checkbox"/>	
10. Is there a description of any potential benefits to the participant or to others that may reasonably be expected from the research?	<input type="checkbox"/>	<input type="checkbox"/>	
11. Are appropriate alternative treatments or procedures that may be advantageous to the participant disclosed?	<input type="checkbox"/>	<input type="checkbox"/>	
12. Is there a statement describing the extent to which the confidentiality of records identifying the participants will be maintained?	<input type="checkbox"/>	<input type="checkbox"/>	
13. For research involving more than minimal risk, is there a description of what compensation may be available if an injury occurs as a result of the research to include where further information may be obtained?	<input type="checkbox"/>	<input type="checkbox"/>	
14. Are points of contact provided for the participant to contact for answers to questions about the research, research participant's rights, and in the event of a research-related injury to the participant?	<input type="checkbox"/>	<input type="checkbox"/>	
15. Is at least one of the points of contact someone other than the investigator or project team members whom the potential participant can contact to verify the validity of the project?	<input type="checkbox"/>	<input type="checkbox"/>	
16. Is there a statement that participation is voluntary and that refusal to participate or a decision to terminate their participation will involve no penalty or loss of benefits to which the participant is otherwise entitled?	<input type="checkbox"/>	<input type="checkbox"/>	
17. Is there a statement that a veteran participant will not be required to pay for care in a VA research project except for any applicable co-payments unrelated to the research project?	<input type="checkbox"/>	<input type="checkbox"/>	
Additional Required Elements			
These elements are required if applicable to the project. If not present, contact the investigator immediately and ask for submission of a revision.	YES	NO	N/A
1. Is there a statement that the particular treatment or procedure may involve risks to the participants (or to the embryo or fetus if the participant becomes pregnant) which are currently unforeseeable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Does the document include anticipated circumstances under which the participant's participation may be terminated by the investigator with the participant's consent?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Are there any additional costs to the participant that may result from participation in the research consistent with the federal laws concerning veteran's eligibility for medical care and treatment?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Is there a statement concerning the consequences of a participant's decision to withdraw from the project and procedures for orderly termination of participation by the participant?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Is there a statement that significant new findings developed during the course of the project that may relate to the participant's willingness to continue participation will be provided to the participant?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Is the approximate number of participants that that will be involved in the project stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Is there a statement regarding any payment the participant is to receive?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. Is there a statement concerning any schedule of payments the participant is to receive?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Is there a statement that federal agencies such as the FDA, OHRP, and the GAO, may have access to the records?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. If an FDA-regulated test article is involved, is there a statement that the FDA may choose to inspect research records that include the participant's individual medical records?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section 4: Missing Required Documents

Check one of the following:

- ☐ No required project documents were missing from the initial submission.
- ☐ Based on an administrative review of the project, the following required documents were not submitted as part of this application.

Document	Date PI Contacted	Form of Contact	Date Received

Add additional rows as needed

Section 5: Issues Requiring Resolution

Check one of the following:

- ☐ No issues require further resolution.
- ☐ Based on an administrative review of the project, the following issues must be resolved prior to the project being scheduled for Board review.

Issue	Date PI Contacted	Form of Contact	Date Resolved	What was resolution

Add additional rows as needed

Section 7: Assigned VA Central IRB Coordinator Recommendation

1. All documents and all administrative issues have been resolved for this PI/SC New Project Application and it is ready for review by the Board. The following type of review is appropriate with this project:

- ☐ Expedited ☐ Convened Board

2. The following documents have been prepared as applicable: *(Check all that apply)*

☐ Reviewer Checklist for Primary Reviewer Name: _____

☐ Reviewer Checklist for Secondary Reviewer Name: _____

☐ Reviewer Checklist for Informed Consent Reviewer *Name:* _____

☐ Expedited Review Eligibility Determination (VA Central IRB Form 121)

☐ ISO Certification

☐ Privacy Officer Certification

VA Central IRB Coordinator: _____ Date: _____

Section 8: VA Central IRB Administrator Concurrence

Check one of the following:

☐ Process project for review as indicated above.

☐ Process project for review but under ☐ Expedited or ☐ Convened Board review procedures.

☐ Review cannot be scheduled at this time due to the reasons detailed below:

Comments:

VA Central IRB Administrator

Date

Administrative Checklist for Local Site Investigator Applications



Project Information

VA Central IRB Number	
Title of Project	
Principal Investigator	
Risk Category	
Type of Review for LSI Applications	

Checklist Items				
Mandatory Documents Received				
1. Local Site Investigator Application				
2. Electronic Submission of Package				
3. Study Team Biosketches				
4. Local COI Determinations				
Other Documents Received as Applicable				
1. VA Research Consent Form (VA Form 10-1086)				
2. Local HIPAA Authorization				
3. Local Recruitment Materials/Sripts				
4. Voice/Photo Consent (VA Form 10-3203)				
5. Investigational Drug Information Record (10-9012)				
6. Participant Instructions				
7. Questionnaires or Surveys				
8. Case Reports				
Other Documents Not Listed				
Document:				

This is checklist _____ of _____.

Checklist Items						
Issues to be Addressed for All Studies						
1. There is an active MOU and FWA is updated. If a CBOC is listed as a site, it is included on an FWA for which the VA Central IRB is listed as an IRB of Record.						
2. The LSI and all members of the local project team have completed VA Human Participant/Good Clinical Practice Education within one year of application submission.						
3. There are no COIs identified or a management plan has been identified for review.						
4. The LSI Application is signed by LSI, Supervisor, and ACOS/R&D of the site.						
1. No changes were made in the Informed Consent document except for site POC information.						
2. No changes were made to the HIPAA authorization except for site POC information.						
3. No changes were made to the recruitment materials except for site POC information.						
4. There are no modifications in any of the participant instructions, surveys, questionnaire, or scripts.						
5. There are no changes in the model photo/voice consent except for POC site information.						
6. There are no changes in the Investigative Drug Information Record except for POC site information.						
7. The site has not identified any other						

committee reports that need to be considered by the VA Central IRB in their review of the project such as Biosafety or Radiation Safety.						
Comments:						

Missing Required Documents

Check one of the following:

- ☐ No required project documents were missing from any of the local site
- ☐ Based on an administrative review of the project, the following required documents were not submitted as part of this application.

Site	Document	Name of Individual Contacted	Date Contacted	Form of Contact	Date Received

Add additional rows as needed

Section 5: Issues Requiring Resolution

Check one of the following:

- ☐ No issues required further resolution.
- ☐ Based on an administrative review of the project, the following issues must be resolved prior to the project being scheduled for Board review.

Site	Issue	Name of Individual Contacted	Date Contacted	Form of Contact	Date Resolved	Resolution

Add additional rows as needed